A legal-ethical analysis of reproductive endocrinologists' right to refuse ovulation induction to patients with diminished ovarian reserve

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Abstract

Purpose Review of the legal and ethical basis for reproductive endocrinologists to refuse ovulation induction to patients with diminished ovarian reserve.

Methods The Lexis-Nexis search engine was used to perform a legal review pertaining to refusal of treatment. Ethical opinions of medical organizations were also reviewed.

Results Federal antidiscrimination laws provide legal recourse for patients with diminished ovarian reserve who are denied ovulation induction. However, the same laws also permit refusal of care when there is bona fide medical justification to decline services. In addition, the codes of ethics for relevant professional organizations support physicians' decisions to refuse treatment when treatment is futile.

Conclusion Although it is ethically and legally permissible to deny ovulation induction to patients with diminished ovarian reserve when medically justified, refusal may invite retaliatory litigation. Counseling remains a cornerstone in directing these patients to options with more potential for success, such as donor eggs and adoption.

Keywords Ethics · Diminished ovarian reserve · Ovulation induction · Discrimination · Liability

Introduction

Diminished ovarian reserve associated with aging is a commonly encountered obstacle predictive of poor IVF success rates ([1–4]; Fig. 1). For many patients, diminished ovarian reserve will prohibit them from ever conceiving their own genetic offspring [5]. For those patients who insist on having their own genetic offspring or cannot afford donor eggs, their frustration becomes apparent. It is not uncommon for reproductive endocrinologists to be confronted by patients with diminished ovarian reserve who are adamant about pursuing ovulation induction despite being informed of the poor chance of success [6]. The dilemma whether or not to allow these patients to proceed with ovulation induction raises perplexing legal and ethical issues. On one hand, patients should be given autonomy to pursue desired treatment, while on the other hand, reproductive endocrinologists should be comfortable in refusing care to patients with diminished ovarian reserve for whom the treatment prognosis is very poor without fear of legal recourse. The federal antidiscrimination laws provide a potential avenue for patients with diminished ovarian reserve who are denied access to infertility services to file suit against reproductive endocrinologists and IVF facilities [7, 8]. The same federal antidiscrimination laws also permit physicians to refuse to provide services when refusal is medically justified [9–11]. For those patients with diminished ovarian reserve whose chances of achieving pregnancy are nonexistent, it is easy to predict the medical justification defense would prevail. However, the limits of the medical justification defense are not as clear for those patients who can conceive but whose chances of conceiving are low. Patient autonomy remains a salient value, and denying ovulation induction to patients who remain adamant after being fully informed of the low probability

Capsule Medically justified refusal to provide ovulation induction to patients with diminished ovarian reserve is legally and ethically permissible but requires cautious application.

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Fig. 1 Age is the single most important factor affecting the probability of success with assisted reproductive technology

Adapted from 2006 Assisted Reproductive Technology Report: Section 2—ART Cycles Using Fresh, Nondonor Eggs or Embryos (Part A), CDC Division of Reproductive Health, http://www.cdc.gov/art/ART2006/sect2_fig5-15.htm#14

of success may invite unwanted retaliatory litigation with claims that the refusal is motivated by a desire to protect a facility's IVF success rate.

The purpose of this legal-ethical analysis is to discuss the procreative reproductive rights of patients with diminished ovarian reserve seeking infertility services and the rights of reproductive endocrinologists to refuse treatment to these patients.

Materials and methods

Legal cases and federal and state statutes pertaining to refusal to provide patient care and futility of treatment were reviewed using the LexisNexis legal research engine. LexisNexis is a commercial online legal research engine for legal-related materials commonly used by attorneys, law students, judges, and paralegals. Legal research engines are important in the legal profession to reinforce legal arguments. The United States legal system operates under the principle of *stare decisis*, which is a system of legal precedents to ensure that the courts deliver consistent rulings on similar legal issues. Thus, prior rulings are helpful to courts in deciding cases.

In preparation for this article, the following keywords were used in LexisNexis as well as a Medline search: *reproductive medicine, assisted reproductive technology, infertility, fertility treatment, in vitro fertilization, ovulation induction, age, discrimination, disability, healthcare, diminished ovarian reserve, follicle stimulating hormone, ovarian reserve tests, conscientious refusal,*

ethics, and medical futility. Legal cases, statutes, and ethical opinions of the American Medical Association (AMA), American Congress of Obstetricians and Gynecologists (ACOG), and American Society for Reproductive Medicine (ASRM) regarding reproductive rights of patients to seek infertility care and the rights of reproductive endocrinologists to refuse treatment to patients with diminished ovarian reserve were analyzed.

Results

Federal antidiscrimination laws that are applicable to fertility clinics

The federal antidiscrimination laws provide a potential avenue for infertility patients who are denied services to seek legal recourse against reproductive endocrinologists and fertility clinics. The Americans with Disabilities Act (ADA) of 1990 defines disability as a physical or mental impairment that substantially limits one or more major life activities. Within the context of the ADA, reproduction is a major life activity [7]. In *Bragdon vs Abbott*, the US Supreme Court upheld a decision finding a dentist liable for discrimination against an HIV-seropositive patient [12]. In this case, Dr. Bragdon refused to fill a cavity of an asymptomatic HIV-seropositive patient, Ms. Abbot, because of his concern that treating her in his office would pose a direct threat to the health and safety of others. He insisted that the dental procedure be performed in a hospital setting and not in his office to reduce the risk of transmitting infection. After

Bragdon performed the procedure in the hospital, Abbot successfully sued him for discrimination under the provisions of ADA. The US Supreme Court found that being infected with HIV satisfied the definition of disability under the ADA law, even though the patient was asymptomatic. In determining whether or not being infected with HIV should be considered a disability, the court emphasized that HIV imposed a substantial limit on the major life activity of procreation because of the risk of HIV transmission to the offspring. In *Bragdon vs Abbott*, the US Supreme Court said, “Reproduction and the sexual dynamics surrounding it are central to the life process itself.”

In a separate Illinois case, the plaintiff, Charline Pacourek, was an infertility patient undergoing IVF treatment at the University of Chicago. Her employer refused to allow time off from work under their sick leave policy for IVF treatment. Pacourek filed a discrimination suit against her employer and prevailed. The Illinois court in this case held that infertility was impairment and limited the major life activity of reproduction under the provisions of the ADA [13]. In addition, according to the federal Rehabilitation Act of 1973, disability is any physiological disorder or condition, cosmetic disfigurement, or anatomical loss affecting 1 or more of the following body systems: neurological, musculoskeletal, special sense or speech, respiratory, cardiovascular, reproductive, digestive, genitourinary, hemic and lymphatic, skin, and endocrine [8].

Section 12182(a) of the ADA law states, “No individual shall be discriminated against on the basis of disability in the full and equal enjoyment of the services, facilities, privileges of any place of public accommodation by any person who operates a place of public accommodation” [14]. Section 12181(7)(F) of the same ADA law provides that a public accommodation does include the professional office of a health care provider [15]. The ADA is, thus, applicable to any professional office of a health care provider, which would include fertility clinics and reproductive endocrinologists.

Bona fide medical justification defense and futility of treatment

In the event a patient with diminished ovarian reserve makes a claim of discrimination against a reproductive endocrinologist and his or her fertility clinic for refusing to provide treatment, the reproductive endocrinologist will have a chance to rebut the claim of discrimination with a bona fide medical justification defense. Refusing to induce ovulation wouldn't be considered discrimination if the refusal were medically justified. The medical justification defense may include that chances of a successive pregnancy are very poor or futile [16]. The patient making the discrimination claim will then have a chance to argue the medical justification defense is just a pretext and that she

should be afforded an opportunity to pursue fertility treatment. Whether the medical justification defense is reasonable or a pretext will be a fact issue that will be decided by a jury or in a bench trial by the judge.

Determining what constitutes medical justification for refusing to induce ovulation in patients with diminished ovarian reserve is complex and unclear. It is much easier for a reproductive endocrinologist to rebut a claim of discrimination when the chance of achieving pregnancy is close to nonexistent. Oftentimes, however, patients with diminished ovarian reserve do have a chance of achieving pregnancy, but the chance is low.

ASRM guidelines for inducing ovulation for patients with diminished ovarian reserve may be helpful in supporting a bona fide medical justification defense. ASRM defines futility as a treatment that has <1% chance of achieving a live birth, and a very poor prognosis is a treatment for which the odds of achieving a live birth are >1% to 5% per cycle—very low, but not nonexistent [16]. In a review of 2,705 IVF cycles initiated in women aged 40 years and above, the live birth rates were >5% in women 40 years of age with FSH values <12 mIU/mL [5]. In this study, the live birth rate for women 44 years of age and above was only 2.3%. Overall, this study concluded there was a reasonable chance of successful pregnancy (>5%) up until 43 years of age [5]. The authors of this article reference this study only as an example and appreciate this study is not conclusive in setting specific cut-off values for allowing patients to proceed with ovulation induction. There are numerous other studies with varying results looking at predictors of ovarian reserve, including FSH, age, inhibin B, anti-mullerian hormone, leutenizing hormone, and the Clomiphene Citrate Challenge Test. ACOG suggests a less specific and broader definition of futility that may also be helpful in supporting a bona fide medical justification [17]. ACOG proposes that the definition of futility might include “evidence indicating that the suggested therapy cannot achieve its physiological goal”.

Ethical basis to refuse services

The ethical provisions of the American Medical Association (AMA), American Congress of Obstetricians and Gynecologists (ACOG), and American Society for Reproductive Medicine (ASRM) may also be applicable in supporting the decision to refuse services to patients with diminished ovarian reserve.

The AMA Code of Medical Ethics provides that

A physician shall, in the provision of appropriate patient care, except in emergencies, be free to choose whom to serve, with whom to associate, and the environment in which to provide medical care [18].

According to the ACOG Committee Opinion entitled Medical Futility

The construct of medical futility has been used to justify a physician's unilateral refusal to provide treatment requested or demanded by a patient or the family of a patient. Such decisions may be based on the physician's perception of the inability of treatment to achieve a physiologic goal, to attain other goals of the patient or family, or achieve a reasonable quality of life [17].

The ASRM Ethics Committee stated in June 2009 that

Clinicians may refuse to initiate a treatment option they regard as futile or having a very poor prognosis. Referral information should be offered, if appropriate. Decisions about treating or refusing to treat couples and/or individuals always should be patient-centered. Protecting fertility center success rates is not an ethical basis for refusing to treat couples and/or individuals with futile or very poor prognoses. Conversely, care should not be provided solely for the financial benefit of the provider or center [16].

Discussion

It is permissible both legally and ethically for reproductive endocrinologists to deny ovulation induction to patients with diminished ovarian reserve when refusal to provide services is medically justified. It would be medically justified to deny services when the treatment prognosis is very poor or futile. Unfortunately, what constitutes a very poor or futile treatment prognosis in many patients with diminished ovarian reserve is unclear. While it may be clear that an infertility patient with an FSH value in the menopausal range will not achieve pregnancy using her own eggs despite best efforts at ovulation induction, many older patients seeking infertility services have borderline ovarian reserve testing. Because of the ambiguity in interpreting what constitutes a very poor treatment prognosis in patients with borderline ovarian reserve testing, caution needs to be taken in declining services to these patients. In the event that a patient with diminished ovarian reserve makes a claim of discrimination under the provisions of the ADA for refusal to provide services, the reproductive endocrinologist will be given the opportunity to rebut the claim with a bona fide medical justification. The burden will then shift back to the patient making the claim of discrimination that the medical justification defense is just a pretext for pursuing other goals, such as protecting a facility's IVF success rate. Ultimately it will be up to a jury—or

in a bench trial, to the judge—to decide if the reasoning provided by the reproductive endocrinologist to refuse treatment is credible and appropriate.

The ethical provisions of the AMA, ACOG, and ASRM also provide a basis to decline services for patients with diminished ovarian reserve similar to the medical justification legal defense in ADA claims. However, like the legal basis, the ethical basis of declining services oftentimes is not straightforward for patients with borderline ovarian reserve testing.

From a defensive legal prospective, it may be advisable to allow patients with borderline ovarian reserve to proceed with ovulation induction. Refusing ovulation induction in patients who remain adamant after being fully informed of the poor chance of success invites legal retaliation and potentially hard-to-rebut claims that the practitioner may be selfishly motivated by the desire to protect the IVF facility's pregnancy success rate. Although a practitioner may have the best intentions at heart to protect a patient from futile treatment, patient autonomy is held as a salient principle. The high regard of patient autonomy combined with the complexity and ambiguity of determining when ovulation induction is futile makes it legally perilous to refuse ovulation induction to patients who remain adamant after have been fully informed of the poor prognosis of success. Counseling remains a cornerstone in directing patients with diminished ovarian reserve to options with more potential for success, such as donor eggs and adoption.

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