Ethics of esthetic procedures in pregnancy☆,☆☆

G. Kroumpouzos, MD, PhD a,b,⁎, L. Bercovitch, MD a

a Department of Dermatology, Alpert Medical School of Brown University, Providence, Rhode Island
b Department of Dermatology, Medical School of Jundiaí, São Paulo, Brazil

Abstract

Article history:
Received 10 September 2018
Received in revised form 4 October 2018
Accepted 5 October 2018

Keywords:
Esthetic procedure
botulinum toxin
cosmetic procedure
ethics

Introduction

Ethical dilemmas arise when clinicians are faced with conflicting and mutually exclusive courses of action that create moral uncertainties (Beauchamp and Childress, 2001). Four ethical principles (respect for patient autonomy [i.e., respect patient’s preferences in medical care], beneficence [i.e., act in the best interests of the patient], nonmaleficence [i.e., do no harm; minimize risk to the patient], and justice [i.e., clinical intervention results in fair distribution of clinical benefits and burdens in a population]) form the foundation of modern bioethics (Beauchamp and Childress, 2001).

In a systematic review of ethical principles in plastic surgery, autonomy was the most common theme (Chung et al., 2009). Cosmetic care is considered to be based on an individual’s autonomous right to seek to become more beautiful (Nejadsarvari et al., 2016). To resolve ethical conflicts often requires prioritizing moral obligations through a process of shared decision making, negotiation, and thoughtful compromise (Mahowald, 2006).

The aim of this article is to discuss ethical dilemmas related to esthetic procedures during pregnancy on the basis of evidence in support of the safety of such procedures during pregnancy. Ethical principles as applicable to mother and fetus and the concept of the fetus as a patient are discussed. Through the analysis of case scenarios, the article highlights reasons for ethical conflicts related to esthetic procedures during pregnancy, such as a lack of high-quality evidence.

Obstetric ethics

Most ethical issues in obstetrics revolve around the maternal-fetal relationship (Digiovanni, 2010). The interests of the pregnant patient (i.e., autonomy, beneficence, and nonmaleficence) are paramount but must be weighed against the risk to the fetus. This is relevant to performing surgical/cosmetic procedures during pregnancy. The maternal-fetal conflict in this context is between the woman’s autonomy and the physician’s judgment of what is best for her fetus (Digiovanni, 2010).

The physician has obligations of beneficence and nonmaleficence to the fetus, which becomes a patient at the age of viability (around 24 weeks’ gestation) or when the mother confers this status on her fetus. Patienthood of the fetus can be established by virtue of personhood or its moral status, which is not required to be independent from its mother’s status (Chervenak et al., 2007). Beneficence-based obligations are considered incongruent for the fetus when the procedure increases fetal risks. The approach of the American College of Obstetrics and Gynecology (ACOG) to ethical decision-making is outlined in the Table.

Evidence related to the safety of esthetic procedures during pregnancy

The classification of the safety of interventions and medications during pregnancy has generally been based on in vitro mutagenicity studies, laboratory animal studies, and accumulated human experience. There is virtually never a high-quality, prospective, randomized, controlled trial to address fetal safety.

The most minimally invasive cosmetic procedures, such as cryotherapy, shave/punch removal, or electrocautery destruction of benign lesions, are considered safe during pregnancy because they have stood the test of time (Kroumpouzos, 2017; Trivedi et al., 2017). Procedures performed under local anesthesia, such as those mentioned, are considered safe because of negligible fetal risks associated with the usual volumes of local anesthetic agents. There are no controlled or prospective studies of the aforementioned procedures...
Ethical dilemmas related to esthetic procedures during pregnancy

Ethical dilemmas that are relevant to esthetic procedures during pregnancy often arise from a lack of high-quality evidence (arising from randomized controlled trials) with regard to the safety of such procedures. However, health care providers should consider that generating these types of data for esthetic procedures is virtually impossible because of the ethical restrictions on performing relevant studies during gestation.

Does the absence of data from randomized controlled studies always constitute a significant evidential deficit when it comes to ethical decision-making? The question eventually boils down to whether physicians who perform esthetic procedures may, in certain cases, decide to lower the bar with regard to the quality of the data. For example, one may consider accepting the results of a large series that compares adverse fetal outcomes as good evidence when performing an esthetic procedure with background rates in the general population. This may help address ethical dilemmas insofar the evidence is clearly communicated to the pregnant patient; however, some physicians may argue that evaluation of fetal risks with these types of data is not flawless.

Solving ethical dilemmas relevant to esthetic procedures during pregnancy in an evidence-based manner can be challenging, especially because there is neither consensus among experts nor a generally accepted gold standard of quality assessment (Stretch, 2008). The needs and values of the patient should be considered in the ethical decision-making process (ACOG, 2007), and fact counseling should be nondirective so that patient autonomy is not compromised. The health care provider should weigh the principles underlying each of the arguments made and decide whether one ethical principle has more merit than others in the ethical conlict with respect to the mother’s autonomy and nonmaleficence as good evidence when performing an esthetic procedure with background rates in the general population. This may help address ethical dilemmas insofar the evidence is clearly communicated to the pregnant patient; however, some physicians may argue that evaluation of fetal risks with these types of data is not flawless.

Solving ethical dilemmas relevant to esthetic procedures during pregnancy in an evidence-based manner can be challenging, especially because there is neither consensus among experts nor a generally accepted gold standard of quality assessment (Stretch, 2008). The needs and values of the patient should be considered in the ethical decision-making process (ACOG, 2007), and fact counseling should be nondirective so that patient autonomy is not compromised. The health care provider should weigh the principles underlying each of the arguments made and decide whether one ethical principle has more merit than others in the ethical conflict with respect to the mother’s autonomy and nonmaleficence as good evidence when performing an esthetic procedure with background rates in the general population. This may help address ethical dilemmas insofar the evidence is clearly communicated to the pregnant patient; however, some physicians may argue that evaluation of fetal risks with these types of data is not flawless.

Table
American College of Obstetrics and Gynecology guidelines for ethical decision-making

|   |   |
|---|---|
| 1. | Identify the decision makers. |
|   | a. Assess the patient’s capacity to make a decision. |
|   | b. Identify a surrogate decision maker for incompetent patients. |
|   | c. In the obstetric setting, the pregnant woman with decision-making capacity is the appropriate decision maker for the fetus. |
| 2. | Collect data, establish facts, try to recognize personal values and bias to remain objective, and use consultants as needed. |
| 3. | Identify all medically appropriate options, including those raised by the patient or family or by consultants. |
| 4. | Evaluate options according to the values and principles involved. |
|   | a. Gather information with regard to the values of the primary stakeholders, especially the patient. |
|   | b. Eliminate options that are morally unacceptable to all parties. |
|   | c. Re-examine remaining options according to the interests and values of each party. |
| 5. | Identify ethical conflicts and set priorities. |
|   | a. Define problem in terms of ethical principles involved (e.g., beneficence, autonomy). |
|   | b. Does one principle appear more important than others in this conflict? Is one course of action better than others? |
|   | c. Consider respected opinions about similar cases, if they exist. |
| 6. | Select the most ethically satisfying (that can be best justified) option. |
| 7. | Reassess the decision after acted upon to determine whether the best possible decision was made and what lessons can be learned. |

Guidelines adapted from American College of Obstetrics and Gynecology Committee on Ethics, 2007.

During pregnancy. However, in most cases, retrospective series of such procedures have not shown any substantial fetal risks.

Informed consent

The informed consent process should include providing information about risks, benefits, and alternatives as they apply to the fetus and pregnant patient (Schwager and Bercovitch, 2013). Legally and ethically, informed consent requires that the patient be provided with sufficient pertinent information upon which a reasonable patient might make an informed decision, that the patient be free of coercion, and that the patient have sufficient decision-making capacity and comprehension to make a decision with regard to the intervention (Schwager and Bercovitch, 2013).

Setting realistic expectations before performing cosmetic surgery is an important aspect of the informed consent process (Nejadzarvari et al., 2016). Disclosure of information should be done by the health care provider in an unbiased, nondirective way. Central to achieving informed consent is the communication between physician and patient. The written consent document should be as thorough as possible (e.g., outline maternal risks and potential fetal risks) but should never be a substitute for the communication involved in the disclosure of information, the conversation that leads to an informed and voluntary consent (ACOG Committee on Ethics, 2009).

In the mutuality of the physician–patient relationship, each is to be respected as a person and supported in the autonomous decisions insofar those decisions are not overridden by other ethical obligations (ACOG Committee on Ethics, 2009). Physicians have a right to conscientious refusal, which refers to the freedom to refuse care to which they may ethically object. This can apply to surgical/cosmetic procedures during pregnancy that may pose significant fetal risks.

Even in this case, health care providers have an ethical obligation to respect the patient’s autonomy by providing accurate and unbiased information about her options; taking into account her priorities, values, and preferences; and facilitating appropriate referrals for a second opinion where appropriate (ACOG Committee on Ethics, 2009). However, health care providers have no ethical obligation to refer patients to a willing health care provider for treatment they consider detrimental to the mother or fetus (ACOG Committee on Ethics, 2013).

Case scenario 1

Jamie is a 27-year-old woman who consults with Dr. M’s clinic periodically for esthetic procedures, such as botulinum toxin type A (BTX-A) and filler injections. She works as a spokesperson on
television, and her appearance is extremely important to her. She is now 30-weeks pregnant, and the last time she had BTX-A injections was a few weeks before she became pregnant. She has noticed that the esthetic effects of BTX-A have worn off and requests another BTX-A treatment. Dr. M advises against this procedure during pregnancy because the effects on the fetus have not been fully studied. Tearing up with disappointment, Jamie insists that she has read that BTX-A is now considered safe during pregnancy and that in a large study “there were no significant fetal risks from BTX-A.” Jamie insists that her appearance is extremely important for her type of work and would like to have the procedure done.

How should Dr. M approach this request?

A) Perform the procedure because that is why the patient came in, and recent data suggest that the procedure is likely safe during pregnancy.
B) Send the patient home without performing the procedure, stating that there is no high-quality data about this procedure during pregnancy and he does not want to put the fetus at risk.
C) Suggest a different procedure that may yield esthetic improvement, but not as good as with BTX-A.
D) Refer the patient to a colleague for a second opinion.

Analysis of case scenario 1

BTX-A likely does not cross the placenta because of its large molecular weight and is not expected to be present in systemic circulation after proper intramuscular or intradermal injection (Tan et al., 2013). Botulism has been reported in 15 pregnant patients and was not associated with birth defects, neonatal loss, or congenital botulism (Badell et al., 2017). In two cases of maternal botulism, infant serum was taken, and no botulinum toxin was detected (Tan et al., 2013).

Most data on BTX-A during pregnancy are derived from retrospective reviews of inadvertent or intentional exposures. A review of case reports/series of BTX-A injections during the first trimester of pregnancy revealed two miscarriages; however, these associations with fetal demise are unclear because both women who miscarried had a history of miscarriage (Kroumpouzos, 2017). A large Allergan series of BTX-A during pregnancy (232 exposed patients during pregnancy) was published recently and showed rates of spontaneous abortion and fetal defects similar to background rates in the general population (Brin et al., 2016). These data indicate that BTX-A administration during pregnancy is likely not associated with fetal/neonatal loss and birth defects.

By performing the procedure (Option A), Dr. M respects the patient’s autonomous decision; however, the well-being of the fetus takes priority over the cosmetic needs of the mother. The fetus lacks the autonomy to consent to exposure to the drug and must depend on the mother and physician to look after its interests. Based on existing data on BTX-A during pregnancy, the physician may consider that the procedure bears only a very remote risk to the viable fetus and proceed with the procedure. This decision can be ethically challenged, especially because the existing data—although of good quality—cannot serve as a gold standard. Also, the provider should perform thorough fact and risk–benefit counseling prior to obtaining an appropriate informed consent.

Refusing to perform the procedure because of a lack of high-quality data and possible fetal risks (Option B) fulfills the principle of nonmaleficence toward the fetus. This is an appropriate ethical choice when the physician appreciates an evidential deficit. However, the health care provider should advise the patient that, although one should keep the bar high with regard to safety data quality, there are no data from randomized controlled trials for esthetic procedures during gestation. Communicating uncertainty should be done in a way that does not diminish patient autonomy (Han, 2013), and the physician should not attempt to impose his or her own values on the patient (ACOG Committee on Ethics, 2013).

To suggest a different procedure that the physician may consider safer (Option C) is an ethically acceptable option and fulfills the principle of nonmaleficence. However, most alternative esthetic procedures lack controlled data during pregnancy as well and are not as effective as BTX-A for dynamic wrinkle correction. A thorough discussion of the pros and cons of alternative procedures is required, and the patient’s autonomy is crucial to the final decision-making.

Finally, a physician who declines to perform a procedure may offer a referral for a second opinion (Option D) because another, likely concordant, opinion may be useful for the patient. This is an ethically appropriate course of action that fulfills the principle of patient autonomy and can be applied when the physician has reservations about performing the procedure during pregnancy and/or the patient cannot reach a decision after thorough, nondirective fact counseling.

Case scenario 2

Niki had several sclerotherapy sessions before her pregnancy. She is now 27 weeks pregnant and more bothered by her spider and reticular leg veins than before. She visits her dermatologist, Dr. Sanson, and requests sclerotherapy treatment even though she is aware that some improvement in her prominent lower limb spider and reticular veins may occur spontaneously postpartum. Dr. Sanson refuses to perform the procedure and advices that it is best to wait until the pressure placed on the pelvic veins during pregnancy is relieved postpartum to have the most effective treatment. Dr. Sanson advises the patient that some sclerosant solutions are known to cross the placenta. Niki is disappointed because she believes that at this stage of her pregnancy, there are no risks for the fetus. She is adamant about having the procedure.

At this point Dr. Sanson should:

A) Perform the procedure because several series have not shown any fetal risks with sclerotherapy during pregnancy.
B) Deny the procedure because the fetal risks have not been studied well in the second trimester.
C) Recommend conservative measures, such as compression, leg elevation, and lifestyle changes.
D) Recommend an alternative esthetic procedure, such as laser treatment, that may be safer during pregnancy.

Analysis of case scenario 2

Varicose, reticular, and spider veins that develop during pregnancy may improve postpartum, and most authors suggest that one should wait at least 6 to 12 months after pregnancy prior to treating the veins (Kroumpouzos, 2017). According to the German Society of Phlebology, sclerotherapy is absolutely contraindicated during the first trimester of pregnancy and after the 36th week of gestation, the latter being a period during which the hypercoagulable status of gestation is most pronounced (Pannier and Rabe, 2006; Rabe et al., 2004). However, a study that compared 45 patients treated with sclerotherapy using sodium tetradecyl sulfate and 56 patients treated conservatively did not show any differences in pregnancy outcomes between the two groups (Abramowitz, 1973). This was corroborated by a retrospective analysis of case reports and series on sclerotherapy with common sclerosants during undetected pregnancy (Reich-Schupke et al., 2012).

Performing the procedure as requested by the patient (Option A) fulfills the principle of patient autonomy. However, the fetus is viable (fetal patienthood can be established at this gestational age), and
fetal risks may exist with sclerotherapy, but there is no absolute contraindication for sclerotherapy during the second trimester of pregnancy. Nevertheless, there are insufficient safety data with regard to sclerotherapy during each trimester of pregnancy with any of the commonly used sclerosants.

Furthermore, pregnancy-induced hypercoagulability, which is most pronounced during the third trimester, is not entirely absent at 27 weeks of gestation. Pregnancy hypercoagulability has been associated with risks such as deep venous thromboembolism (Battinelli et al., 2013; Kroumpouzos and Cohen, 2001). The ethically relevant empirical information on sclerotherapy during pregnancy may not reach the status of good evidence. Therefore, it is ethically problematic to choose Option A. By denying the procedure (Option B), Dr. Sanson prioritizes beneficence-nonmaleficence, which is ethically appropriate.

However, denying the procedure may cause patient dissatisfaction if no alternative treatment options are provided. A recommendation of conservative measures (Option C) is both indicated and supported by the literature. This course of action fulfills the ethical principles of beneficence and nonmaleficence. Offering a safer, alternative treatment (Option D) such as long-pulsed, Nd:YAG 1064-nm laser may be ethically acceptable; however, such laser treatments are not as effective as sclerotherapy for deeper reticular veins and have adverse effects that patients may be unwilling to risk. An extensive discussion of the risks and benefits of laser treatments should be done, and the risk of post-treatment recurrence before the end of gestation should be emphasized. Based on this scenario, discouraging the patient from laser treatment would be most appropriate course of action.

Conclusions

Ethical dilemmas related to esthetic procedures during pregnancy often reflect a conflict between the woman’s autonomy and physician’s judgment of what is best for the fetus. The well-being of the fetus and the moral obligation of no harm (beneficence-nonmaleficence) take priority over the cosmetic needs of the mother. Ethical conflicts with regard to cosmetic procedures often arise out of a lack of high-quality evidence and reflect the difficulty of obtaining safety data based on randomized controlled trials during pregnancy. However, as more data become available and more clinical experience accumulates, a broader consensus will likely develop on the safety of various esthetic procedures during pregnancy.

Appendix A. Supplementary data

Supplementary material related to this article (Patient Page) is provided with the link below:

https://doi.org/10.1016/j.jiwd.2018.10.003.

Patient Page

In addition to the Women’s Health Highlight featured article, we have developed a Patient Page which is included as supplemental material of the article. The Patient Page provides essential health information written for patients from experts in the field including easy-to-understand explanations of dermatologic diseases and treatments. This minimizes the risk of misinformation from internet and social media that can cause patient frustration and anxiety. The Patient Page is a concise, informative sheet that the Health Care Provider can download, print and provide to their patients to prompt them to ask relevant questions and begin focused doctor/patient dialogue. Click on the supplemental material at the end of the Women’s Health Highlight article to view/print the Patient Page.

References

Abramowitz I. The treatment of varicose veins in pregnancy by empty vein compression sclerotherapy. S Afr Med J 1973;47(14):607–10.

American College of Obstetrics and Gynecology Committee on Ethics. Opinion No. 390: Ethical decision-making in obstetrics and gynecology. Obstet Gynecol 2007;111(5):1479–87.

American College of Obstetrics and Gynecology Committee on Ethics. Opinion No. 439: Informed consent. Obstet Gynecol 2009;114(2 Pt 1):401–8.

American College of Obstetrics and Gynecology Committee on Ethics. Opinion No. 578: Elective surgery and patient choice. Obstet Gynecol 2013;122(5):1134–8.

Badell ML, Rimawi BH, Rao AK, Jamieson DJ, Rasmussen S, Menney-Delaney D. Botulinum during pregnancy and the postpartum period: A systematic review. Clin Infect Dis 2017;66(Suppl. 1):S30–7.

Battinelli EM, Marshall A, Connors JM. The role of thrombophilia in pregnancy. Thrombosis 2013;2013:516420.

Beauchamp T, Childress J. Principles of biomedical ethics. 5th ed. New York, NY: Oxford University Press; 2001.

Brin MF, Kirby RS, Slavotinek A, Miller-Messana MA, Parker L, Yushmanova I, et al. Pregnancy outcomes following exposure to onabotulinumtoxin A. Pharmacoeconomics Drug Saf 2010;29(2):179–87.

Chevrenak FA, McCulloch LB, Levene ML. An ethically justified, clinically comprehensive approach to peri-viability: Gynecological, obstetric, perinatal and neonatal dimensions. J Obstet Gynecol 2007;27(1):3–7.

Chung KC, Pushman AG, Bellif LT. A systematic review of ethical principles in the plastic surgery literature. Plast Reconstr Surg 2009;124(5):1711–8.

Digiovanni LM. Ethical issues in obstetrics. Obstet Gynecol Clin North Am 2010;37(2):345–57.

Han PK. Conceptual, methodological, and ethical problems in communicating uncertainty in clinical evidence. Med Care Res Rev 2013;70(1 Suppl):145–36.

Kroumpouzos G. Cosmetic procedures in pregnancy: A reappraisal. Skinmed 2017;15(2):93–6.

Kroumpouzos G. Cosmeceuticals and cosmetic surgery in pregnancy: A reappraisal. Skinmed 2017;15(2):93–6.

Levine ML. Bioethics and women across the lifespan. New York, NY: Oxford University Press; 2006.

Nejadsaravi N, Ebrahimi A, Ebrahimi H, Hashem-Zade H. Medical ethics in plastic surgery: A mini review. World J Plast Surg 2016;5(3):207–12.

Pannier F, Rabe E. Sclerotherapy for varicocoes. Hautarzt 2006;57(1):19–20 22–5.

Pannier-Fischer F, Gerlach H, Breu FX, Guggenbichler S, Zabel M, et al. Guide lines for sclerotherapy of varicose veins. Dermatol Surg 2004;30(5):687–93.

Reich-Schupke S, Leiste A, Moritz R, Altmeyer P, Stücker M. Sclerotherapy in an undetermined pregnancy - A catastrophe? Vasa 2012;41(4):243–7.

Schwager Z, Bercovitch L. Dermatoethics in pregnancy. In: by Kroumpouzos G, editor. Test Atlas of Obstetric Dermatology, Philadelphia, PA: Lippincott Williams & Wilkins publishers; 2013.

Strech D. Evidence-based ethics—what it should be and what it shouldn’t. BMC Med Ethics 2008;9:16.

Tanj M, Kim E, Koren G, Bozzo P. Botulinum toxin type A in pregnancy. Can Fam Physician 2013;59(11):1183–4.

Trivedi MK, Kroumpouzos G, Murase JE. A review of the safety of cosmetic procedures during pregnancy and lactation. Int J Womens Dermatol 2017;3(1):6–10.