

Review article

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Voluntary termination of pregnancy (medical or surgical abortion): forensic medicine issues

DOI 10.1515/med-2016-0062

received June 25, 2016; accepted June 27, 2016

Keywords: Forensic medicine; Medical abortion; Surgical abortion; Informed consent

Abstract: In Italy, Law 194 of 22 May 1978 provides for and regulates the voluntary termination of pregnancy (VTP). Medical abortion became popular nationwide after Mifepristone (RU-486) was authorized for the market by AIFA (Italian Drug Agency) in July 2009. We searched articles in medical literature database with these terms: “medical abortion”, “RU486”, “surgical abortion”. We also searched laws and judgments concerning abortion in national legal databases. Ministerial guidelines were searched on official website of Italian Ministry of Health. We found many medical studies about medical and surgical abortion. We found also ministerial and regional guidelines, which were analyzed. From the point of view of legal medicine, the issues related to abortion with the pharmacological method consist in verifying compatibility and consistency with the safety principles and the parameters imposed by Law n. 194 of 1978, using off-label Misoprostol, what inpatient care should be used and informed consent. The doctor’s job is to provide the patient with comprehensive and clear information about how the procedure will be performed, any complications and the time period needed for both procedures.

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The Authors have no conflict of interest or any financial support

1 Introduction

In Italy, Law 194 of 22 May 1978 provides for and regulates the voluntary termination of pregnancy (VTP). As a matter of fact, in the first ninety days, the decision-making power is with the woman requesting the abortion. The text of the law does not refer to how the termination of the pregnancy is to be performed, whether through pharmacological or surgical techniques. Medical abortion became popular nationwide after Mifepristone (RU-486) was authorized for the market by Italian Drug Agency (AIFA) in July 2009. Surgical abortion is a well-established technique. We have focused on medical abortion, since it is a newer technique.

2 Methods

We searched the medical literature database PubMed using these terms: “medical abortion”, “surgical abortion”, “RU486”. We searched also on national legal databases (such as www.foroitaliano.it) for laws and judgments on abortion. Ministerial guidelines were searched on the official website of Italian Ministry of Health (www.salute.gov.it).

3 Results

Many articles (for example reviews and case reports) were found about abortion, medical or surgical; the most important were analyzed. National ministerial guidelines were found and analyzed; we found also a small number of regional guidelines. We reported here the most impor-

tant judgments. Only one national law regulates abortion (Law 194/78); we analyzed the fundamental articles of this law.

4 Discussion

4.1 Law 194 of 22 May 1978

In Italy, Law 194 of 22 May 1978 provides for and regulates the voluntary termination of pregnancy (VTP). Introducing termination of pregnancy regulation in Italy for the first time, this law justifies VTP to protect the health of pregnant women, citing Art. 32 of the Italian Constitution.

With a judgment prior to said law (no. 27 of 18 February 1975), the Constitutional Court had declared Art. 546 of the penal code to be illegitimate, deeming not only danger to the life of the mother but also to her health a cause of justification for abortion. In fact, Art. 546 was punishing whoever caused *“the abortion of a consenting woman and the woman herself, even when the danger caused by the pregnancy to the physical and psychological balance of the pregnant woman was ascertained, without the occurrence of the state of necessity described in Art. 54 of the penal code.”* [1].

In this regard, the Supreme Cassation Court ruled that the sacrifice of the unborn, whose protection is proclaimed in the first paragraph of Art. 1 of Law 194/78, be allowed, deeming the protection of the mother’s physical or mental health to be preeminent (Cass. no. 6464 of 07/08/1994; Cass. no. 12195 of 12/01/1998).

The justification of VTP varies with the progress of the fetal development according to deadlines that the law establishes in three periods: within 90 days of pregnancy, from 90 days until the moment the fetus has reached the possibility of independent life and after the fetus has reached such condition [2].

Art. 4 of Law 194/78 regulates the VTP procedures for the first 90 days of pregnancy, *“A woman whose circumstances are such that continuation of pregnancy, childbirth or maternity would entail a serious danger to her physical or mental health, due to her state of health or economic or social or family conditions, or the circumstances in which conception occurred, or the expectation of anomalies or malformations of the unborn, shall seek the aid of a public clinic or a social-health facility or a doctor of her choice.”*

Art. 5 of Law 194/78 has established the process of this practice: upon the pregnant woman’s request, the physician shall determine the state of her pregnancy and, if there is no emergency, issue a document to her that she

will also sign, and ask her to defer for 7 days. After seven days, said woman will be able to go to one of the authorized facilities to get an abortion. If a state of emergency has been determined, the doctor shall issue a certificate allowing her to get an abortion without having to wait seven days.

As a matter of fact, in the first ninety days, the decision-making power is with the woman requesting the abortion, although, in accordance with Art. 5, it is her doctor’s task, *“especially when the request ... is motivated by the impact of economic, or social, or family conditions on the expectant woman, to examine together with her and the father of the unborn, with her consent ... possible solutions ... to help her remove the causes that would lead her to terminate the pregnancy ... ”*

It should be pointed out that it is for the woman requesting the abortion to decide whether or not to get the father of the unborn involved, so as to safeguard her health, which is a constitutional right that may not be delegated.

In accordance with Art. 6, after the 90th day, VTP may occur: *“a) when the pregnancy or childbirth present a serious danger to the expectant woman’s life; b) when disease processes have been ascertained to exist, including anomalies or malformations, which present a grave danger to the expectant woman’s physical or mental health.”*

After 90 days of pregnancy, it is necessary that the pathological processes of the unborn child be ascertained by means of medical surveys and not just feared by the expectant mother. After 90 days, the circumstances of conception, economic conditions or social or family reasons are no longer valid criteria to request an abortion.

Art. 7 specifies that the pathological processes legitimizing VTP after the 90th day *“are to be assessed by a physician from the obstetrician-gynecological services of the hospital where the operation is to be performed, which shall certify their existence. Said physician may call upon the collaboration of specialists...”* The same article also states that *“when the possibility of independent life of the fetus exists, the termination of the pregnancy can only be performed in the case referred to in subparagraph a) of Art. 6 and the doctor performing the operation should take all necessary measures to safeguard the life of the fetus.”*

The clinical evaluation of the *“possibility of independent life of the fetus,”* which was not specified in chronological terms by the legislature, is therefore up to the doctor and should be performed according to each individual case, the structure in which one operates, and the progress of technical and scientific knowledge.

As required by Article 12, an abortion should be requested personally and exclusively by the expectant

woman. Only two situations require the opinion of a third party: when she is under the age of 18 (according to the provisions of Art. 12) or in case of interdiction for mental infirmity (art. 13). However, her consent is necessary in both cases.

In the case of underage women requesting VTP in the first 90 days of pregnancy, there are two possible scenarios. If the underage expectant woman claims serious reasons, due to which summoning her parents or guardians is not advisable, the doctor should deliver a report to the judge who supervises the guardianship within 7 days of the request; within 5 days, the latter is to contact her and, after hearing her reasons, may authorize the abortion with an act not subject to appeal. If instead she consents to summoning her parents or guardians, their consent is requested. Should they be against it or disagree with each other, the process previously described shall be implemented.

As for a woman under interdiction, the abortion request may be submitted by her or her guardian or her husband if he is not the guardian. The opinion of the guardian should always be taken into account.

Health personnel may freely decide to claim conscientious objection, as provided by Art. 9 of Law 194/78, through which a professional is exempt from performing procedures and activities aimed at causing an abortion. Conscientious objection may not be invoked in emergencies or for activities prior or subsequent to the activities that are specific to or necessary for an abortion, as also stated by Cass. Pen., no. 14979 of 27.11.2012 (“*includes as crime of refusing to perform one’s duty when an officiating doctor refrains from assisting a VTP patient in the performance of activities prior or subsequent to the activities that are specific to or necessary for an abortion ... as for drug-induced termination of pregnancy, the court ruled that the exemption from conscientious objection is limited only to the provision and administration of abortifacient drugs, but it does not extend to subsequent phases*”).

4.2 Medical abortion

Please note that the text of the law does not refer to how the termination of the pregnancy is to be performed, whether through pharmacological or surgical techniques. When the law was enacted, the only abortion method that could be done with safety margins was through surgery; in those years, medical abortion was known only theoretically and was performed with highly toxic drugs.

Medical abortion became popular nationwide after Mifepristone (RU-486) was authorized for the market by AIFA (Italian Drug Agency) in July 2009.

WHO considers medical abortion a suitable and safe method for terminating pregnancy until the ninth week of gestation; after this period, the incidence of incomplete abortions, side effects and complications related thereto increase. In Italy, this practice is possible up to the seventh week of pregnancy.

The pharmacological protocol most widely used for medical abortion involves the oral intake of RU-486 followed by a prostaglandin analog, the most used being Misoprostol (200 mg of Mifepristone and 800 micrograms of Misoprostol) [3]. The second drug should be taken between 36 and 48 hours after taking Mifepristone [4].

Mifepristone is an antagonist drug of the progesterone receptor and glucocorticoids. Although not fully understood, the abortive mechanism is likely due to the endometrial environment changing from progesterone inhibition.

Common medical VTP side effects are pain and abdominal cramps, nausea, vomiting, fatigue, headache, dizziness, fever, profuse bleeding [5]. The most serious and less frequent complications are: *Clostridium sordellii* and *Clostridium perfringens* infection, uterine ruptures, thrombotic thrombocytopenic purpura and hypersensitivity [6-8].

Taking RU-486 is contraindicated in case of suspected ectopic pregnancy, when an IUD is in place, severe anemia, allergies, hereditary porphyria, coagulopathies or ongoing treatment with anticoagulants, treatment with long-term corticosteroids and chronic adrenal insufficiency [9].

As an abortifacient, the efficacy of pharmacological abortion is defined as the complete expulsion of the conceptus without the need to resort to surgical procedures. The effectiveness of this method shows a fairly wide variability: 92-98% within 49 days of gestation according to studies, decreasing respectively to 83% and 77% at 56 and 63 days of gestation [10].

4.3 Legal medicine issues

From the point of view of legal medicine, the issues related to abortion with the pharmacological method consist in verifying compatibility and consistency with the safety principles and the parameters imposed by Law n. 194 of 1978, using off-label Misoprostol, what inpatient care should be used and informed consent.

The legitimacy of the medical abortion technique is absolutely indisputable; Law 194/78 is the only law regulating abortion, and it does not place any obligation on the method to be applied. Indeed, Art. 15 of this law promotes the research for ever more modern techniques to obtain the voluntary termination of pregnancy that will respect mental and physical integrity. Compared to the surgical method, medical abortion may be considered as more mindful of physical integrity.

As for Misoprostol, its use in medical abortion practice was off-label until April 2014. Misoprostol is a synthetic prostaglandin E1 analog that began as a drug for gastric ulcer treatment. In medical VTP practice, this drug was used with an off-label indication, as it was originally indicated as “anti-ulcer, anti-acid.” In April 2014, the AIFA published a statement in the Official Gazette no. 83 of 9 April 2014 authorizing Misoprostol for the market, a medicine containing the active ingredient Misoprostol, indicated specifically “for the medical termination of intrauterine pregnancy, following the use of Mifepristone, to be implemented until the 49th day of amenorrhea.”

Regarding medical abortion regulation, the Ministry of Health published “Guidelines on voluntary termination of pregnancy with Mifepristone and Prostaglandins” on 24 June 2010, specifying clinical and nonclinical, “admission criteria of patients to the treatment based on: - Pregnancy in utero with amenorrhea within 49 days/gestational age ultrasound dating within 35 days - VTP request document/certificate - Duly completed and signed informed consent - Willingness to be hospitalized until completion of procedure - Willingness to undergo remote monitoring, within 14-21 days of discharge ...

The following should be taken into consideration: **Clinical criteria:** a) special clues that may be: - Fear of surgery - Allergies to anesthetics - Anatomical difficulties in accessing the uterine cavity b) absence of contraindications, such as: - Suspected ectopic pregnancy or adnexal masses not previously diagnosed (symptomatic uterine fibroids); - IUD in place - Severe anemia (Hb<7g/dl) - Allergy to one of the drugs - Hereditary porphyria - Coagulopathies or ongoing treatment with anticoagulants - Ongoing treatment with corticosteroids or adrenal insufficiency - Other serious systemic diseases (evaluation to be made by the doctor in charge, e.g., severe liver, kidney or respiratory disease, uncontrolled hypertension, cardiovascular disease (angina, valvular disease, arrhythmias, cardiac insufficiency) uncontrolled seizures, hyperpyrexia from unknown cause, complicated diabetes, immune deficiency (like AIDS) current intestinal disorders, etc.) - Breastfeeding - Seizures, cardiovascular and cerebrovascular diseases, current intestinal disorders.

Nonclinical criteria: in view of the fact that the procedure is partly self-managed by the patient, it should be made sure first of all that she has clearly understood the steps that she’ll have to take and the possibility that she will complete them in full (for example, patients who are very anxious, have a low threshold of tolerance to pain, have an overly precarious home life conditions or cannot promptly reach the Obstetrics-Gynecology Emergency Room should be carefully evaluated for exclusion). - Given the above, it should be made sure that foreign women properly understand the procedure and the symptoms that they should determine for themselves (intensity of pain, bleeding, etc.). - Medical abortion is not recommended for minors, and therefore minors without parental consent should be excluded from this procedure, as completing the therapeutic program in this situation is expected to be difficult... “ [11].

The publication of these ministerial Guidelines has given rise to several discussions at the national level, in both the political and healthcare field. The main disagreement involves the guideline requiring inpatient care to undergo medical abortion.

In terms of healthcare, the legislative power of Italy’s Regions is concurrent with that of the government; therefore, the government sets forth the fundamental principles that the Regions must follow, but the Regions can self-regulate (e.g., by issuing Guidelines) while respecting the Constitution, EU constraints and international obligations. Therefore, in this specific case, based on the interpretation of Law 194/78 and the acknowledged value of ministerial guidelines, each Region has specified independently whether to perform medical abortion as an inpatient care or day hospital treatment. Some Regions have decided to follow the ministerial guidelines requiring hospitalization for three days (Day one: signing informed consent and taking RU-486, Day two: clinical monitoring, Day three: taking Misoprostol and monitoring until the abortion material is expelled) with a follow-up after 14-21 days.

Other Regions have opted to let the patient choose between inpatient care with continuous hospitalization for three days or the day hospital alternative.

In Europe and the US, Misoprostol is administered in a day hospital setting; some studies suggest to take it independently at home [12, 13].

As for ministerial nonclinical criteria, some inconsistencies may be observed: first, a procedure “self-managed” by the patient is mentioned, but it’s not clear what that can be as the Ministry instructs that medical abortions be performed only with hospitalization for three days. Additionally, exclusion criteria are listed that may appear difficult for the physician to evaluate and whose value is

questionable, as for example, the patient's anxiety level, low pain threshold, overly precarious home life conditions or inability to quickly reach the emergency room. Finally, the medical abortion procedure is not recommended for minors who request it without the consent of their parents, clearly going against the provisions of Art. 12 of Law 194/78.

Another important legal medicine issue is the health provider's collection of a valid informed consent from the patient before resorting to VTP, whether medical or surgical. In this regard, the ministerial medical VTP guidelines of June 2010 point out some items to be considered when collecting consent; besides the need to resort to inpatient care and the possible complications deriving from this process, the guidelines specify that the patient should be provided with comprehensive information about the different abortion techniques that are available to her, referring particularly to the surgical technique. Therefore, the Ministry recommends that information be provided about the fact that surgical abortion "*requires a short hospital stay, usually 4-8 hours.*"

The regional Guidelines should list in a schematic way the main features of surgical and medical abortion techniques, so that the patient can make informed choices regarding which technique she should opt for.

4.4 Informed consent for surgical or medical abortion

As for the surgery, it is appropriate to specify that it usually takes a short time and is performed on a specific date, rarely before the 7th week of pregnancy, thus allowing more time for the patient to reflect; bleedings don't last long and pains are infrequent. Complications that should be disclosed include: possible infections, incomplete abortion, uterine perforation, possible surgical uterine damage. As for medical abortion, it should be specified that it takes several days and is performed no later than the 49th day of pregnancy, it does not require anesthesia and the bleeding lasts much longer than with the surgical treatment with more frequent abdominal pains. The complications to be disclosed are the ones already listed.

Informed consent is fundamental, as it allows the patient to decide consciously and with validity which abortion procedure to request, and it should include a conversation between the doctor and the patient, as well as the provision of written informational material that can be carefully consulted by the patient. The doctor's job is not to suggest a technique over another, unless there are specific contraindications to the use of a technique,

but to provide the patient with comprehensive and clear information about how the procedure will be performed, any complications and the time period needed for both procedures.

5 Conclusions

Text of the law 194/78 does not refer to how the termination of the pregnancy is to be performed, whether through pharmacological or surgical techniques. When the law was enacted, the only abortion method that could be done with safety margins was through surgery. WHO considers medical abortion a suitable and safe method for terminating pregnancy until the ninth week of gestation. In Italy, this practice is possible up to the seventh week of pregnancy. The doctor's job is not to suggest a technique over another, unless there are specific contraindications to the use of a technique, but to provide the patient with comprehensive and clear information about how the procedure will be performed, any complications and the time period needed for both procedures.

Conflict of interest statement: Authors state no conflict of interest

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