New anathemas: conscientious objection and freedom to access drugs in emergency contraception

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Summary

Emergency contraception is by definition a critical situation difficult to cope with in the medical profession. The freedom of a woman requesting it represents a crucial issue likely to come across the conscientious objection expressed by the prescriber. This possibility, which is properly regulated and applied in circumstances such as voluntary termination of pregnancy, artificial insemination and animal experiments, failed instead to be given a proper legal and regulatory framework in emergency contraception.

Among the methods most commonly used in emergency contraception, the so-called “morning-after pill” is becoming an increasingly common practice nowadays: it is a Levonorgestrel-based formulation (LNG) readily available and easy to administer (as a single or double dose), whose very low cost and minimum set of symptoms associated with possible side effects have made it the "emergency drug".

This paper analyzes scientific knowledge on LNG and focuses on studies demonstrating that this medicine does not affect the stage subsequent to human embryo formation and its implantation. This aspect, which was at the very heart of the debate on conscientious objection expressed by a physician, fails to find adequate support in the existing scientific evidence. Our wish is that there might be proper regulatory provisions on the issue allowing the prescriber to exercise the right, consistent with his/her personal ethical, moral and religious beliefs, while at the same time also allowing women to have freedom of access to the drug.

KEY WORDS: emergency contraception, levonorgestrel, conscientious objection.

Background

The possibility of resorting to emergency contraception, also known as post-coital prophylaxis (the so-called “morning-after pill”), as a method to prevent an unwanted pregnancy, started a heated ethical-deontological debate in Italy following the marketing of medications containing the pharmacologically active principle, as introduced by Health Ministry Decree dated 26th September 2000 (AIC / UAC no. 510/2000). The Italian medical community has long been divided by tensions animated by ethical, moral, philosophical and religious beliefs culminating in the recognition of conscientious objection for healthcare professionals. This indisputable choice has been examined taking into account both its impact on the possibility to access the drug and in terms of its legitimacy, since the refusal to dispense the treatment is not contemplated in the case of emergency contraception. This option is instead contemplated ex lege for other medical procedures such as abortion, artificial insemination and animal testing. However, conscientious objection in emergency contraception takes on special relevance in that it is not a choice made in a public facility, where the role can be taken over by another healthcare professional hence securing the right of a woman to use the medicine, but most of the time it occurs inside a dualistic relationship (woman - prescriber) and in a state of urgency (inherent to the process): these conditions may generate areas of major concern in situations where the doctor refuses to prescribe the medicine.

This article will examine the background of scientific knowledge on emergency contraception, since its introduction in the '60s, and will subsequently discuss the specific problems associated to conscientious objection expressed by healthcare professionals.

Background information on the “morning-after pill”: a typical example of the modulation of scientific knowledge over the time

Post-coital contraception through the use of high doses of estrogen (ethyl estradiol or etilistibestrolo) was used with sexual assault victims in the 1960s. The early 1970s saw the rise of a method, based on the com-
bined use of estrogen and progesterone, known in North America with an eponymous (Yuzpe) from the physician who had first proposed it (1). In 1976, mechanical devices (IntraUterine Device) were introduced in post-coital contraception, with the aim to minimize the side effects associated with the estrogen/progesterone combination (particularly nausea and vomiting related to the estrogen component) until the early 1980s when medicines containing levonorgestrel only were introduced.

In the '90s, the obvious advantage associated with simple oral administration in emergency contraception encouraged pharmacological research for further products synthesis. Today there is a number of preparations that can be assumed by mouth such as: LNG with or without progesterone, drugs that act by blocking progesterone receptors such as mifepristone and gonadotropin receptor antagonists (GNRH-a).

The World Health Organization (WHO) has played a key role in promoting research towards the most effective method with the fewest side effects. The first study sponsored by WHO compared two double-blind methods: the former, proposed as early as 1973 by Kessleru (2), was based on the administration of levonorgestrel alone in two 0.75 mg doses, and the latter was developed by Yuzpe; 2000 women were enrolled in 21 centers in North America, Europe, India, China and Australia. The results showed that the administration of LNG alone was more effective than the Yuzpe method, even when the data were normalized as a function of pregnancies expected compared to the day of sexual intercourse; LNG proved to be much more effective the earlier its administration with respect to sexual intercourse and caused a lower side effect ratio. These results, published in 1998, formed the rationale for the introduction of LNG-alone therapy in many countries (3). In 2002, WHO published the results of a second study on the effectiveness and side effects of two different modes of administration of LNG and a single dose of mifepristone. In a double-blind trial, 4136 women were enrolled in 15 research facilities distributed in 10 different countries; the administration of two 0.75 mg doses of LNG, given 12 hours apart, after unprotected sexual intercourse, was compared to one single 1.5 mg dose of LNG and to a single 10 mg dose of mifepristone after 5 days. The total number of pregnancies was essentially the same with the three modes of administration (4).

As for side effects, the comparison between the Yuzpe method and the administration of LNG shows for the latter a lower incidence of all side effects, statistically significant (p <0.01), as regards nausea, vomiting and asthenia (5). In line with scientific evidence, WHO policy urged for immediate changes in emergency contraception strategies, emphasizing the absence of contraindications in its use while at the same time including LNG-based formulations in the list of pharmaceuticals recommended to all countries. In two subsequent publications, WHO described the conditions for the adoption of guidelines and for the development of health policies in the various countries (6).

Today, LNG-based emergency contraception has been approved and the drug has been registered in over 100 countries although its popularity has not reduced the recourse to abortion: indeed, if the woman or the couple, after the use of emergency contraception, continue to have sexual intercourse without a planned contraceptive practice, an unwanted pregnancy will be very likely to occur (7). In theory, emergency contraception can act at various stages of the reproductive cycle such as ovum transport and its development, its implantation and function of the corpus luteum.

Nevertheless, having regard to LNG mechanism of action, scientific knowledge considers it effective only with respect to pre-ovulatory phase. According to well-established experimental evidence, LNG can inhibit or delay the development of the follicle and ovulation, when administered in the follicular phase of the cycle until the day before ovulation (the thirteenth day in a normal cycle length) (8-18). If LNG is administered on the day of ovulation or the day before the formation of the corpus luteum, ovulation may still occur: this implies that the drug is no longer effective for a large period of the cycle.

As a matter of fact, there is no proof of LNG contraceptive effects when administered after ovulation, nonetheless a central aspect of the debate in our country is exactly the use of LNG in the early luteal phase, and in particular whether such administration may affect the morphology of the endometrium during the 6-10 days which represent the time-window before the formation of the corpus luteum. On this point, since the early 2000s scientific research has unanimously highlighted that LNG (when taken in the 1.5 mg recommended dose) affects neither the endometrium morphology, nor tissue markers of receptivity during the luteal phase of the cycle (8-18). These findings can be summarized as follows: “Emergency contraception based on a single 1.5 mg dose of LNG works by inhibiting or delaying ovulation but it does not prevent fertilization nor implantation and has no adverse effects on pregnancy” (19).

It should be noted, however, that some recent studies, published in the 1980s, indicated endometrial alterations following LNG administration and represented by an “asynchronous” development between the epithelial and stromal components (20-22) and a reduction in the concentration of estradiol and progesterone receptors (23). These studies are generally referred to for the purposes of demonstrating the effects of LNG after fertilization of the ovum and, in particular, against the implantation of the product of conception.

In more recent studies, however, histological samplings of the endometrium in women taking LNG were collected around the expected time for implantation and neither histological or morphometric alterations nor biochemical markers or endometrial receptors were identified (16, 17, 18, 24).

Apart from this, the results obtained are consistent with the pharmacological characteristics of LNG which, being a progestin drug, has a positive impact on gestation hence it favours the implantation of the fertilized...
ovum rather than inhibiting it. In conclusion, LNG inhibits or delays ovulation if taken during the first half of the cycle while there is no scientific evidence that the doses used for emergency contraception are effective in inhibiting some of the events occurring after ovulation, like tubal transport and implantation of the fertilized embryo in the uterus (8, 25, 26). Last but not least, scientific evidence yet to be confirmed indicate that LNG has an inhibitory effect on sperm transport and capacitation, which may partly explain its action in emergency contraception (13, 27).

In conclusion, summing up the indications of two outstanding international scientific bodies – FIGO (International Federation of Gynecology & Obstetrics) and ICEC (International Consortium for Emergency Contraception) (28), current knowledge on LNG mechanism of action:

a) provide uniform and sound evidence that the drug acts only as a contraceptive by preventing or delaying ovulation if taken prior to it;

b) indicate that the drug is extremely effective as a contraceptive: no pregnancy was reported in the two only studies determining preovulatory acquisition through hormone analysis, whereas it proved ineffective when taken after ovulation thus confirming that the drug is not able to prevent embryo implantation (29, 30);

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c) confirm that most studies exclude that the drug acts only as a contraceptive by preventing or delaying ovulation if taken prior to it;

d) demonstrate the absence of effects on the implantation of the fertilized egg both in human embryos in simulated conditions of endometrial environment (32, 33) and in animals (34, 35);

e) confirm, finally, that at present there is no conclusive knowledge on LNG action on sperm.

The national debate on conscientious objection: does outdated scientific knowledge support a shareable moral principle?

In our country, further to the introduction of emergency contraception, the debate focused on the mechanisms of action of the drug and, in particular, whether or not it acts before the implantation of the fertilized egg. The starting point of case law lies in the decision of TAR Lazio of 2001, in which it was noted that “legal regulations do not provide a clear indication as to the initial moment of human life”. The administrative court further stated that “… the licensed drug acts by causing subtle effects at a time prior to the implantation of the fertilized egg in the womb”.

This remark, scientifically correct, was used in favour of the liberalization of interruption techniques prior to the implantation of the ovum: a possibility introduced by ministerial decree AIC / UAC no. 510/2000 which had authorized LNG marketing. A possibility which was therefore excluded from the existing regimen for the voluntary termination of pregnancy governed by law n. 194/78.

From a legal perspective, the crucial issue was to clearly define when exactly is the beginning of the biological process by which a new individual is formed and, ultimately, the initial moment of human life: a topic to which legal doctrine, jurisprudence, theology, ethics, biology and bioethics tried to contribute but failing to propose, as a result of strong ideological conflicts, solutions formulated within a specific regulatory framework.

Strictly speaking, de iure conditio, only at birth the subject acquires full legal capacity, pursuant to article 1 of the civil code, nonetheless the fetus is not devoid of human quality nor of the subjectivity associated to fundamental rights and as such it becomes the recipient, in specific contexts, of precise juridical norms.

The remark is supported by law, given that in 1978 the legislator did not have all the relevant elements available to identify the very first moment of life. In these circumstances, the legislator preferred to use abstract expressions such as the need to “protect human life from its beginning” (art. Law n. 1 194/78); nonetheless, he already referred to termination of pregnancy to describe the legally relevant point at which the reproductive process deserves such special legislative guarantees that it can be interrupted. The legislator’s intention was, from the outset, to use the term pregnancy to cover the entire reproductive cycle and not just a single phase of it. Such an explanation is clarified by the law’s literal wording: it declares the principle of life protection from its very beginning and not from the implantation of the fertilized egg.

Jurisprudence, using expressions sometimes difficult to interpret and today also incomprehensible in the light of available scientific evidence, described the drugs used for emergency contraception as post-coitus contraceptives, just to accentuate the inhibition function of the treatment. Moreover, since these drugs were not classified as abortive agents but as pre-implantation agents, they do not fall within the guarantees established under law n. 194/78, at least based on the most common interpretation of the law, that makes them applicable only to termination of pregnancy after implantation of the fertilized egg.

This legal debate carries with it the meaning of the expression non abortive termination used for emergency contraception, whose techniques or pharmacological practices dealing with the events prior to the implantation of the ovum, interrupt the pre-implantation reproductive cycle and are therefore defined as non abortive in the sense that they are not influential in pregnancy. This legal interpretation corroborated the possibility of resorting to emergency contraception in cases other than termination practised within the meaning of law n. 194/78 following admission to appropriate health care facilities. As a matter of fact, since this practice cannot be described as a termination of pregnancy, it was and is performed in any private place and determines an area of contraception, fully liberalized, situated between egg fertilization and its implantation.

In these circumstances, the debate focused mainly on ethical aspects related to dispensing prescriptions, since the health-related ones were resolved thanks to
the free availability of pharmaceutical drugs. In 2003, the National Federation for the Order of Medical Doctors and Dentists (press release n. 60/2003) had clarified that the standing committee on the revision of the Code of Medical Ethics had not judged necessary, when discussing the morning-after pill, to examine the legal and bioethical issues it raised, but had intended to consider only the practical deontologic aspects. Indeed, the Order considered article 19 of the Code of Medical Ethics in force in 1988 as the most correct behavioural guidance and best suited to the doctor’s freedom of conscience. In 2006, with the approval of the new code of ethics, article 22 explicitly stated that the doctor could refuse practices running counter his/her conscience and clinical beliefs “... unless this behavior is likely to cause an immediate and serious harm to the health of the patient”.

The National Bioethics Committee (CNB) in its “Note on emergency contraception”, approved on May 28th 2004, in response to a question on the possibility of refusing prescription in emergency contraception, came to the conclusion that “... it has to be unanimously upheld the possibility for the doctor to refuse the prescription or administration of LNG .... based on his/her right to appeal to a ‘conscience clause’ in the light of the constitutionally recognized importance of safeguarding the unborn baby which motivates the abstention”.

Finally, NBC stated that the doctor had to “... Whatev-er his opinions, provide the woman thorough informa-tion about the use of the drugs in question and their possible mechanisms of action.” It should be pointed out that in a postscript some NBC components emphasized the need for the interests of all parties involved in emergency contraception to be duly taken into account and noted that “... the possible extension of the doctor freedom is not without consequence for the ability of women to access without additional incon-venience ... emergency contraception”. Moreover they invited authorities and relevant institutions ... to supervise and if necessary to ensure that throughout the national territory ‘conscience clause’ exercised by doctors working within the NHS does not involve any major difficulties and a de facto restriction of freedom and civil and social rights to the detriment of women”.

However, the motivational process justifying the lawfulness of denying a prescription was supported by the “plurality of hypothetical mechanisms of action of lev-norgestrel (LNG): on the one hand, based on well-es-tablished data reported in the literature, the interference with ovulation, likely to be inhibited or delayed, or with the entire process of ovulation; on the other hand, the actual possibility of a postfertilization action, lead-ing in particular to the modification of the uterine lining or of tubal motility, should fertilization occur”. This view was reiterated by NBC in an Opinion considering the “possibility that under different conditions, LNG may interfere with embryonic development, once fertilization has occurred”.

In other words, an alleged post-ovulatory action was still supported despite scientific evidence to the contrary in 2004 already: this discrepancy between scientific evidence (denying a contraceptive mechanism of action of the morning-after pill) and the national debate (whose essential motivation in favour of a derogation from the prescription in the event of conscientious objection doctors resides precisely in this eventuality) is at the heart of the ethical - deontological problem in our Country.

Even in a more recent opinion, delivered on 25th February 2011, NBC refers to scientific information not supported by adequate evidence as well as to patient information leaflets, to sustain the possibility of direct action on the embryo implantation. In particular, NBC explains that this leaflet (available on the net, 36) reports of a “possible elimination of the embryo”.

An analysis of scientific evidence, previously conduct-ed, shows that this possibility is not supported by studies of adequate methodology and it is based, instead, on uncertain scientific evidence and not corresponding to the actual conditions of use of the morning-after pill: it is based on uncontrolled results or implemented via outdated research protocols and not confirmed in sub-sequent studies.

However, this background information is now present in the discussion on the problem and scientific evi-dence fails to turn it into outdated knowledge. What is missing at the moment is a discussion based on criti-cal review of available knowledge and carefully assessing consolidated evidence, which deny any signific-ant LNG effect in the post-fertilization stage (37). The national debate on conscientious objection appears, therefore, limited to a parallel drawn between the morning-after pill and abortion, based on the erro-neous belief that the former acts on the fertilized ovum and, therefore, on a biological life albeit in its potential of prospective individual development.

The phenomenon of conscientious objection finds its roots in the relationship between conscience and law: it particularly refers to the relationship between ethical imperatives (moral rules), dictated by human con-science, and legal norms, prescribed by the State. Al-though in some cases ethical rules and legal norms may coincide (as for example when transgression of the moral precept corresponds, in terms of law, to the consummation of crime), they generally regulate dis-tinct areas separated one from the other. Indeed, hu-man conscience, understood as “inner faculty” and “in-ternal capacity” of the person aimed at “seeking the ethical basis of life and its ultimate meaning”, and law, understood as a set of rules governing the relationships within a civil society, while consisting of two con-comitant dimensions or modes that guide and enhance human behaviour, have distinct spheres of operation, since they have a different source, a different function and different purposes.

Nonetheless, under certain circumstances, ethics and law may come to a confrontation, and also possibly be colliding hence causing a conflict of loyalty within the decision-making sphere of the person. Any possible collision between the two different existential dimensions will emerge with respect to specific sensitive matters touching on the inner sensitivity of the person (abortion, divorce, genetic manipulation and bioethical issues, euthanasia, living wills, artificial insemination, military service, capital punishment) in that they fall, by
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their very nature, within both the public sphere and the sphere regulated by moral conscience. An inner conflict of the subject may arise in these cases: a conflict of loyalty caused by the contrast between the need to enforce the cogency of the legal norm, recognized as binding and mandatory, and the moral imperative to comply with the dictates of individual conscience, which is resolved by recognizing the latter prevailing over requirements of the law. This position is shared by the case-law of the Italian Constitutional Court, which has recognized the constitutional significance of the individual conscience of the human person, described as central for the whole system of human rights. In particular, the judges have found that, “in terms of constitutional values, individual conscience is safeguarded by protecting the fundamental freedoms and inalienable rights recognized and guaranteed to man as an individual, pursuant to art. 2 of the Constitution, since the latter cannot be fully and effectively safeguarded without a corresponding constitutional protection of the privileged and intimate relationship of man to himself which represents their spiritual and cultural base as well as their ethical and legal foundation. According to this perspective “since individual conscience is given constitutional relevance as the creative principle which makes possible the reality of fundamental human freedoms and as the realm encompassing the different expressions of inviolable rights of the individual in social life, it enjoys constitutional protection commensurate to the need for these freedoms and rights not to be unreasonably limited as a result of barriers or unjustifiable impediments to the multifaceted discretionary power expressed by individual conscience” (38).

In the light of the legally founded centrality of human conscience, the question then arises as to the relevance of the associated deeper issues based both on religious values and on secular reasons, especially in case of claims potentially conflicting with the legislative dictates. In some cases, conscientious objection is defined as a substantial form of dissent against the formal requirements of law, while at the same time being an irrepressible exercise of individual freedom of choice.

Conclusions

With regard to emergency contraception, conscientious objection is exercised in the absence of a legal regulatory framework as opposed to other “sensitive” areas, such as abortion, artificial insemination and animal testing, which are instead governed by specific regulations.

A comparison between the personal choices of conscience expressed by a doctor under the current regulation reveals a coherent legislative policy underlying laws 194/78 and 40/2004: it is a decision concerning deontological positions dealing with the beginning of the biological experience of the human being, both having regard to its termination and to a non-natural route to procreation. Conscientious objection in animal experimentation is different because the choice concerns every citizen eventually involved in the procedure, and it is related to the respect of the biological being with respect to a practice (testing) devoid of immediate interest to another human being nor substantially affecting his possible choices and demands. However, having regard to the exercise of conscientious objection in procedures associated with the beginning of human life, in the field of the “morning after pill” the technical interpreter grasps the core of an irreconcilable discrepancy. In a field characterized by strong and radical issues for each individual, the use of scientific evidence to support the possibility of a “moral” choice is found inappropriate (in general terms) and irrelevant (when referring to the mechanism of action of LNG).

Leaving aside the aspects leading to general considerations as to the “neutrality” of scientific research that cannot be addressed in this paper, we have examined the specific aspects of the problem. A scientific assumption (the antifertility action of the drug) is at the very heart of the national debate on emergency contraception, which assumption is largely overcome by a background of unambiguous and established knowledge reported in the international literature. Maybe it would be appropriate to reconsider the refusal to prescribe the “morning-after pill” by basing that not on outdated scientific knowledge but rather referring it to the sphere of freedom (of conscience) which appears to be a central moment in the life of each individual. This freedom is to be exercised according to choices (moral, ethical, religious) whose legitimacy cannot be questioned, because they are naturally pertaining to a principle of individualist expression of the person, which permeates every state regulation and (not incidentally) our Constitution. In other words, the possibility to deny the prescription should be declared as a value in itself, as belonging to an autonomous choice of a physician, without the apparent “coverage” of scientific knowledge: only in this perspective (related to an absolute and moral choice), there can be a sound basis for a discussion that can represent the starting point of a debate getting to the root of the problem which, in the present case, has not to do with the dynamics of an issue as sensitive as conception of human life but with broader social issues relating to the individual’s perception of a free and conscious sexuality. In this context, it is clear that the choice to deny prescription encroaches on and limits the freedom of women; but this is the only true point of the question. It is, therefore, an area in which the choices made so far have been tentative. If no doctor can be denied the right to conscientious objection with respect to the prescription of LNG, it is nonetheless desirable to regulate this choice through national laws (i.e. in ordistin terms in each local area) and made explicit by the doctor to the patients at the time of choice, so that the woman does not gain sudden and unexpected knowledge in the emergency situation. In the balance necessary to settle any radical opposition of instances (in this case: the individual conscience of the doctor vs personal freedom of the woman) it is clear that mediation can only refer to the possibility for the holder of a
right recognized by the state (the woman in emergency contraception) to choose in advance her interlocutor from whom will depend the exercise of the right under discussion insofar as he/she will be the direct interface in charge of implementing the procedure authorized by the state (prescription of the drug).

It is clear in any case that the physician who declares himself/herself as an objector has, again, the duty to properly refer the patient to structures (such as counseling) that in any case, except for health reasons, will be required to prescribe LNG. This is how their activity will be part of the notion of public service, responsible for implementing and giving effect to all applicable state regulations and, among these, even those in the field of emergency contraception.

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