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Review

Informed consent and Percutaneous Endoscopic Gastrostomy (PEG): the difficulties of a single European viewpoint

Samir Sukkar[1], Rosario Barranco[2], Francesco Ventura[2], Andrea Molinelli[2]

[1]San Martino Hospital, Department of Clinical Nutrition and Dietetics, Genova, Italy; [2]University of Genova, Department of Legal and Forensic Medicine, Genova - E-mail: Rosario.barranco@libero.it

Summary. Percutaneous Endoscopic Gastrostomy (PEG) is a surgical technique by which, connecting the gastric cavity to the external part of the body, it is possible to introduce nutritional blends into the gastrointestinal tract by means of a feeding tube. This operation, invasive and not without complications, may be legitimately and lawfully carried out by the doctor once the beneficiary has provided a valid and conscious consent. In fact, a correct patient information, together with a PEG consent, represent the key elements of lawfulness, thereby expressing the voluntary, conscious and free adhesion of the beneficiary. They represent an essential link between the doctor's duty to cure and the personal right of the patient to self-determination. The delicate nature of this subject is demonstrated by the fact that all European Union Countries enact informed consent regulations, thus stressing the mandatory compliance to same as the basis of fairness of medical practice. In Europe, however, whenever there is an urgent need for this operation, in the case of a patient incapable of providing a valid and conscious consent, a different PEG health management is practised. To that effect, in order to ensure the consistency of the European citizens' rights, a joint and shared management with the EU state members would be preferable with regard to the implementation of the percutaneous endoscopic gastrostomy regarding patients incapable of self-determination.

Keywords: informed consent, percutaneous endoscopic gastrostomy, person lacking capacity

Introduction

The effectiveness of artificial enteral nutrition is confirmed by multiple and influential evidence. The "ESPEN" guidelines emphasize the utmost importance of an adequate nutritional intake in order to improve the quality of life, prolong survival of dysphagic patients and provide an access with a minor impact from the point of view of body image, mainly in persons still leading an active social life (1, 2).

Percutaneous Endoscopic Gastrostomy (PEG) is a surgical technique by which, connecting the gastrointestinal tract to the external part of the body, it is possible to introduce nutritional blends into the gastrointestinal tract by means of a feeding tube (3). This technique was first described by Gauderer in 1980 (4). The key variables involved in the choice to do a PEG in clinically compromised conditions are related to psychological, religious, ethical, but primarily legislative reasons. After all, the latter aspect represents a highly discussed element.

Where percutaneous endoscopic gastrostomy surgery is recommended, the doctor may only proceed after having adequately informed the patient and obtained the consent from the beneficiary of the treatment.

Given the paramount importance and awareness of this issue, some international sources have expressed themselves in order to determine the aspects of which beneficiary should be informed; to this regard, the Helsinki Convention stated that "no individual capable of providing his own consent may be enrolled in a study without his free consent to participate in same" and the Oviedo Convention on human rights and biomedicine requires the provision of "adequate information on the purpose and nature of the operation, together with its consequences and risks (Art. 5, paragraph 2).

The problem is even more significant when the patient is incapable of fully understanding the information provided by the healthcare professional and therefore unable to produce a valid and conscious consent. In such situations, the regulations in force in the various European countries appear extremely heterogeneous and one can see a considerable difference in the management of the cases in which the PEG is a highly recommended treatment but the patient is nevertheless incapable of self-determination.

Informed consent versus PEG in European Countries

Italy

On the basis of Italian Law, PEG is legitimized and becomes a lawful act when there is a valid consent on behalf of the patient; this document expresses the free and conscious awareness of the patient with respect to the treatment proposed by the healthcare professional *(Ruling no. 3520/2005)*. A capable person's freedom of choice not only includes the right to be cured and therefore to request the necessary treatment, but also the freedom of choice to refuse any such treatment. The inviolable right to remain passive when faced with certain therapeutic requirements is explained in the second paragraph of Article 32 of the Constitution, which states that no one can be forced to carry out a specific medical intervention unless required by law and, in addition, this in no way may violate the limits imposed by respect for human beings. The individual's right to express an informed consent to the operation is a fundamental principle due to its function of synthesis between the right to health and patient's self-determination. Moreover, under Article 50 of the Penal Code "It is not an offence to violate or endanger a right, with the consent of the person who validly gives same". Therefore, without the informed consent, with the exception of cases whereby medical treatment is obligatory by law or where a necessity exists (Article 54 Criminal Code), a medical operation is considered an unlawful act, even when it is in the patient's interest *(Ruling no. 27751/2013)*.

By virtue of above, in the case of a capable patient, the healthcare professional is obliged to provide in advance, in a comprehensive and complete manner, all the scientific information possible regarding percutaneous endoscopic gastrostomy, together with any normal consequences, even if infrequent, so much so as to appear extraordinary, relative to the balance between risks and advantages of the operation *(Ruling no. 253/2009)*; subsequently, once the patient has been informed, he may consciously decide whether or not to authorize the operation.

However, recent judgements of the Court of Cassation appear partially conflicting and not very clear. In this sense it seems appropriate to cite the judgement of the Court of Cassation, Civil Section I no. 26446/2002 according to which "the doctor is entitled to practise on the patient any therapeutic treatment which he considers necessary to safeguard his health, even without his explicit consent"; furthermore, the Criminal Court of Cassation no. 2437/2009 states that "when the doctor carries out a surgical treatment on the patient different from that to which the informed consent relates and such operation is performed in compliance with the protocols and *legis artis* and is concluded successfully, without any contrary indications from the patient himself, such conduct is irrelevant from a criminal point of view"; on the other hand, the decision of the Criminal Court of Cassation, Section IV no. 5076/2010 seems more ambiguous, according to which "in the event of medical and surgical activities performed without the consent of the patient, this may not automatically infer the responsibility of the doctor" as "the healthcare professional always acts, maybe sometimes mistakenly, for therapeutic or curative purposes which is incompatible, except in exceptional circumstances, with wilful injury" nevertheless "the fact that the disease has been deter-

mined with good intentions to heal another, in no way excludes that, in the meantime, same is and remains a voluntary determined disease. For the purposes of the configuration of the crime of personal injury pursuant to Article 582 of the Penal Code, the generic intent is sufficient which could be determined, as noted, also in medical practice". Indeed, the judgement of the Civil Court of Cassation, Section III, 16543/2011 ruled that "the consensus is so imperative and may not be eliminated just because the operation is correctly carried out, technically, for the simple reason that due to the lack of total information the patient is not in a position to accept the treatment, which means that in any case that part of dignity is damaged which in crucial moments – of physical and/or psychological suffering - characterizes his existence".

Such statements disorientate the healthcare professional, who, faced with the absence of a clear jurisprudential orientation, finds himself in a blatant situation of obvious discomfort when the PEG operation would be highly recommendable in consideration of the clinical situation, involving the maintenance of enteral nutrition over time, although there are alternatives that could be immediately used instead of PEG (e.g. parenteral nutrition).

Further problems may arise in the case where the percutaneous endoscopic gastrostomy is carried out on patients incapable of expressing a valid and conscious consent and incapable of understanding the information concerning the pathology of which they are affected, together with the operation to be carried out.

In this regard, in 2004 Italian lawmakers revised the legal status of the people deprived of all or part of their autonomy. Law 6/2004 introduced the figure of a Court-appointed guardian in order to protect those people deprived of all or part of their autonomy, with the least possible limitation of the ability to act. The appointment of such figure is entrusted to the tutelary judge, a magistrate established at each Italian Ordinary Court, with the task of supervising protection and guardianship. The choice of the Court-appointed guardian is based on the greater possibility of customization of the support offered and the greater agility in its application procedure *(Ruling no. 22332/2011)*. The group of possible beneficiaries of the Court appointed guardian includes all those individuals who "owing to a disability, whether mental or physical, are in the impossibility, either partial or temporary, to provide for their own interests" (Art. 404 Civil Code). Likewise, in the same way as Article 408 Civil Code, the choice of the tutelary judge must take place "with exclusive regard to the care and interests of the beneficiary". The institute is suitable for use in a wide range of cases, ranging from more serious forms of mental distress to situations of mere physical impediment. The Court appointed guardian, as recalled by the Court of Trieste with the pronunciation dated March 11, 2009, expressed a consent in lieu of the beneficiary or otherwise assisted the patient at the moment of decision.

In such situations, the healthcare professional, before proceeding with surgery, must provide thorough information to the patient and Court appointed guardian, who has the duty to protect the interests of the patient, respecting the will of same.

From a practical standpoint, if the PEG is not an inevitable practice and the patient appears incapable and not assisted by a Court appointed guardian, the doctor should implement a less invasive procedure mainly guaranteeing an adequate hydration (such as the placement of a peripheral venous catheter) and request the opinion of the tutelary judge before subjecting the patient to the percutaneous endoscopic gastrostomy.

Rather, in cases where the PEG proves to be a highly recommended and non-deferrable operation, the healthcare professional could act under the state of need, Article 54 of the Criminal Code, according to which "the person committing the fact is not punishable if forced by the necessity to save himself or others from the current danger of serious harm to the person, danger not voluntarily caused by himself, nor otherwise avoidable, provided that the fact is proportionate to the danger".

In this sense, reference is made to the Court appointed guardianship proceedings no. 633/2010: in this case, with regard to a patient in an advanced state of pyschomotor debilitation for which the PEG was necessary, an appeal was made to the tutelary judge to request the appointment of a legal representative in order to proceed, with the consent of same, with the surgical operation. The tutelary judge took the view that in the cases in which the patient is not able to pro-

vide his conscious consent to the operation, but same is nevertheless necessary for this health, it is not possible to demand the informed consent or the appointment of a Court appointed guardian, as the state of necessity, together with the fulfilment of the duties of the exercise of the profession according to the best knowledge and belief, legitimize the doctor's action.

In such situations, the medical-legal orientation is in any case to inform the tutelary judge, who, upon exercising his function of responsibility and protection with respect to the incapable person, authorizes the surgical operation to be carried out.

The Court of Varese, Civil Section I, has also expressed itself on the PEG: in this case, an appeal was made to the tutelary judge, to authorize the administrator of the patient with obvious cognitive impairment, "to express opposition to the adoption of an artificial feeding program of same, refusing a gastrostomy placement, for the importation of an artificial enteral nutrition". Having assessed the case, the tutelary judge "acknowledging the lack of urgency or state of impossibility to delay and having noted that the PEG does not constitute a medical aid which is either additional or different in the scopes and with respect to feeding carried out through a nasogastric tube", stated "in compliance with the health protocols in force", "authorizing the implementation of the artificial enteral feeding system through percutaneous endoscopic gastrostomy, in the times and with the procedures deemed most appropriate on the basis of correct medical science"; such ruling criticizes the opinion of the patient's administrator, being in net contrast with the interests of same; in such cases, it appears correct for the healthcare professional to appeal to the tutelary judge in order to solve the existing contrast between the patient's representative and the correct interpretation of medical science.

In the absence of a full validity of the so-called living will, Italy had supported the hypothesis of a prior nomination of the Court appointed guardian, if the beneficiary should lose, at a later time, the ability of self-determination; a few judgements had welcomed the possibility of appointing a representative beforehand, with the task, in the case of subsequent incapacity of the patient, to express consent or dissent to the medical treatment *(Court of Florence, 22 December 2010; Court of Cagliari, 22 October 2009; Court of Appeal of Cagliari, 16 January 2009)*. On the other hand, additional judgements take on a different orientation, excluding the possibility of a prior nomination of a Court appointed guardian, as the existing law in Italy requires a current inability of the beneficiary to provide for his own interests, orientation which has also been confirmed by the Court of Cassation *(Ruling no. 23707/2012)*.

France

French regulation pertaining to matters of informed consent to medical treatment is embodied in the law entitled "*Relative aux droits des malade et à la qualité du système de santé*" (commonly referred to as *Loi Kouchner*) no. 303 of March 4, 2002, which addresses patients' rights and standards of treatment. This legislation establishes the requirements that physicians must meet so as to guarantee that patients are fully informed and cognizant of the choices regarding their health (5). The terms of the law (Article 1111-2) call for comprehensive information to be given to patients regards their current health status, the need for and urgency of any therapeutic recommendations, the possible treatment options, as well as any potential risks incurred. The information provided must include that regards the consequences of failing to accept treatment, as recommended, by denying consent. According to the law, the limits to information are those posed by "normally predictable, frequent and serious risks." In the face of potentially fatal conditions and non-acceptance on the part of the patient, the physician is obliged to earnestly attempt to persuade him/her to comply with lifesaving measures, if nothing else (Art. 1111-4, par. IV). According to the tenet of *consentement libre et éclairé*, Article 11 states that "*No medical procedure or treatment may be performed without the unrestricted and informed consent of the person and such consent may be withdrawn at any time*". It is the patient's right to appoint a *représentant légal*, who must be consulted and to whom decisions on the patient's behalf are entrusted, with regard to treatment options, were the patient incapable of doing so for him- or herself. Under such circumstances all medical or surgical procedures are prohibited, emergencies excluded, without prior consultation of the designated

appointee. Similarly, a living will is a written statement containing advance decisions, to which healthcare providers must adhere, regarding which life-prolonging treatments or interventions the patient consents to in the event of critical or terminal conditions; it has a 3-year validity and is subject to renewal, in the absence of which its value becomes merely indicative with no binding effects (6). This provision is in stark contrast to Italian law in which the patient's advance decisions do not take precedence over current requirements for consent to medical treatment or absence thereof.

Spain

The dignity of patients is steadfastly advocated under Spanish regulations (see Law no. 42 of November 14, 2002 – *Ley Básica Reguladora de la Autonomía del Paciente y de Derechos y Obligaciones en Materia de Información y Documentación Clínica*, which integrates Law no. 14 of April 25, 1986, *Ley General de Sanidad*). In fact, even a whole section title exemplifies this regard for patients' freedom of choice. The patient's right to be fully informed of any and all interventions concerning his/her health are guaranteed, unless he/she willingly chooses not to be made cognizant, or whenever a "privilege or therapeutic exception" exists, whereby that knowledge may be withheld when deemed capable of seriously jeopardizing the patient's outcome, according to the healthcare provider. A ruling of the Constitutional Court on March 28, 2011 underscores the patients' right to forgo any unauthorized intervention, a right not subject to any arbitrary limitation regardless of illness. It acknowledges the right to autonomous and unfettered self-determination and choice amongst all medical procedures and therapies available, accepting the risks, while reserving the option to refuse them. Apart from by the patient himself, informed consent may be granted in his behalf by a third party whenever the patient is either legally incapable of doing so or otherwise impaired in his/her decision-making, according to a physician's medical opinion; absent any legal representative for consent, a family member or de facto guardian shall give it. The actual impairment resulting from being incapable may be discretionary, allowing the possibility of some ability to decide, on a case by case basis, in matters of one's own health; only when said abilities are deemed insufficient, the legal representative may intervene in the patient's behalf (7).

Advance decisions pursuant to Article 11.4 of Law 41/2002 may be revoked at any time, provided they are via a written statement. Law no. 41 provides for advance decisions and the appointment of a legal guardian or representative in advance, besides setting guidelines for eventual treatment; the rationale of such provisions is to guarantee that the person's will be respected by third parties acting in their behalf.

In contrast to France and Belgium, where living wills have fixed durations of 3 and 5 years respectively, Spanish legislation poses no such limits. Advance refusal of consent to treatment is valid regardless. Nevertheless, there are also some ambiguities in the norms; first of all, this is due to law of the skill, tending to undermine the foundations of advance decisions from a normative viewpoint, thus obliging incapable patients to receive adequate treatments, excepting irreversible conditions; advance decision statements do not encompass current informed consent, given that the will of the patient may have subsequently changed. In this sense, the advance decisions should serve as indications, subject to medical evaluation, also pursuant to Article 9 (Oviedo Convention), according to which "the indications previously expressed must not be applied invariably. If the living will predates the procedure by a reasonably long time and, in the meantime, science has made further progress, there would be some justification to not abiding by it. Under similar circumstances, the doctor should have to make no small effort to be convinced that the living will corresponds to the current situation and therefore still maintains its relevance, especially considering the advances in the medical field." Based on the above, even though Law 41/2002 has met with favour in Spain due to greater autonomy of the patient, it has nevertheless been the object of criticism due to the potential pitfall of driving the concept of individual freedom to extremes (8).

Germany

With reference to incapable patients, albeit a *de facto* institution, confirmed in case law, informed consent still lacks specific normative underpinnings in German legislation. In fact, the Federal Supreme Court declared the legitimacy as well as the binding

nature of patients' advance decisions *(Patientenverfügung)*. According to the Court, it is tantamount to a declaration of intent or settlement and, as such, subject to the general norms applicable. To become effective the Patientenverfügung must precisely envisage the circumstances to which the decisions apply. As a settlement, it may be revoked or amended by the individual at will. The Court envisions the binding nature of the Patientenverfügung under the right to self-determination, considered akin to the tenet of protecting human dignity, pursuant to Article 1, paragraph 1 of the Basic Law (Grundgesetz), which states that any decision made by an individual in full possession of his/her mental faculties, or subsequent lack thereof, must be respected. The substance of the settlement comprises a preamble and an operational part, in which the medications and painkillers to be administered are listed, along with their relative dosing schedules; the text is supplemented by the physician's diagnosis and/or the eventual considerations regarding the possible benefits to the patient were he/she kept alive artificially; the closing consists in an authorization to convey the contents to the general practitioner and/or healthcare providers concerned. In terms of arrangements for management and medical treatment regards the patient's future inability, it also authorizes the Vorsorgevollmacht (advance mandate to manage assets) and the Betreuungsverfügung, i.e. Court appointed guardian (pursuant to the reform law regulating the right to protection and guardianship for the elderly, dated September 12, 1990 - Gesetz zur Reform des Rechts der Vormundschaft und Pflegschaft fürvolljährige Betreuungsgesetz -, BGBl. I 1990, page 2002, in force as of January 1, 1992). Once elucidated in the appointment act, said parties must defer to the will as explicated. Under said circumstances, the Court ruled that, in the face of diverging opinions between physician and administrator regards the terms of the will, the final decision shall rest with the tutelary judge. The living will debate is a longstanding one amongst those directly involved and at the parliamentary and institutional level as well. Indeed the issue was addressed by the 66° Deutsche Juristentag, fostering a clear regulatory framework for the technicalities regarding both the living will and advance decisions alike. In particular, the recommendation is that the Patientenverfügung be in written or documented form, besides being free from defects of consent. Whenever a written living will is lacking and the patient is unable to give his/her consent, the presumable will should be established by a tutelary judge (6).

England

The Mental Capacity Act (MCA) of 2005 (9-10), covering England and Wales, is one the most noteworthy and detailed statutory frameworks for people lacking capacity to make decisions for themselves. A set of key principles constitute the underpinnings of the Act that establishes specific indications concerning persons lacking capacity. First and foremost, a person must be assumed to have capacity, until established otherwise. The practical ramifications are that the type of support and safeguard measures are to be tailored to the individual, so that margins of flexibility are designed into the framework. Decisions regarding care and treatment, in particular, must strive to return the individual to a condition that enables the person to enjoy his or her rights and act freely. Consent regarding acts related to care or treatment, on the part of the person, implies full awareness of the nature, purposes, effects, risks and benefits of such treatments, as well as their realistic outcomes and possible alternatives. The comprehensiveness of the information provided is therefore fundamental. Family members or carers are not called upon as experts to determine the person's capacity to make decisions, although, to have protection from liability with reference to an act of care or treatment, they must however have a reasonable belief that the person in whose behalf they are deciding lacks capacity (hence the term 'reasonable' is not explicitly defined as a formal process, but rather implies reasonable steps to ascertain the person's inability to decide or give consent when needed). The onus to assess whether the person has the capacity to give consent to medical treatment is put on the healthcare professional, as it is the professional's duty to care for the person and determine whether the person accepts treatment. Should there be disagreement amongst healthcare professionals regarding a person's capacity, the case is to be referred to the Court of Protection. A noteworthy aspect of the British Mental Capacity Act, absent from Italian legislation, consists in fact that a person having capac-

ity is entitled to decide in advance whether to consent to specific healthcare treatments, or their continuation, by making provisions for them, as is the case in France and Spain. The advance decision can be either in writing or oral, provided it is made in the presence of one or more witnesses; in either case, precise details regarding the treatments must be included. Equally of note is the feature that the Mental Capacity Act entitles a person to make a lasting power of attorney, which has replaced the preceding enduring power of attorney. It is an instrument whereby a person confers to one or more persons the right to make even healthcare and treatment decisions on his or her behalf (11-12). Decisional power embraces the person's welfare or specified health-related matters. A lasting power of attorney must be appropriately registered before use in a specific registry at the office of the Public Guardian. In the event a person had failed to expressly declare preferences concerning eventual treatments, the doctor decides whether they should be administered, continued or interrupted. Should a conflict of opinion arise, the Court of Protection shall appoint a deputy, defining the scope and term of the appointment (13). Independent mental capacity advocates are appointed whenever the health authorities find no one to consult, apart from healthcare professionals, about the person's best interests.

Discussion

Percutaneous endoscopic gastrostomy (PEG) is a key method of gaining access to the digestive tract, but in most cases, less invasive methods of nutritional support are available and preferable.

The surgical procedure is performed with the patient under local or general anesthesia. During surgery, an incision is made through the skin, muscle layers and gastric wall so as to create a stoma into which the catheter (G-tube) is fitted. The stoma can be created by using at least two different approaches. The first employs an endoscope introduced into the stomach via the mouth and esophagus (PEG). Once inside the gastric lumen, a light at the tip of the instrument is visible through the abdominal wall and guides the surgeon as to the exact location for the incision. The other technique requires open surgery, whereby an incision is made on the middle or left side of the abdomen so as to visualize the gastric wall. A small G-tube is then inserted through an incision in the gastric wall. Stitches around the opening in the stomach wall fasten the catheter in place and then the incision is sutured.

After the placement, the length of the postoperative stay in the hospital often varies, but may be as short as one or two days if the patient's general conditions are otherwise favorable. Usually, the surgical wounds heal within a week after the G-tube placement (14-16).

The PEG is indicated in the following two main circumstances: enteral feeding and bowel decompression (17). In patients who are not able to maintain a sufficient oral intake, PEG provides a long-term enteral access. This commonly includes patients with a chronic and temporary neurological dysfunction, such a individuals with brain injury, strokes, cerebral palsy, neuromuscular and metabolic disorders and impaired swallowing (18). Other important indications are also skull-cervical traumas and surgery of the upper respiratory tract where oral nutrition is excluded. In patients with advanced abdominal cancer causing chronic intestinal obstruction, the PEG may be utilized to decompress the intestinal tract (19).

Absolute contraindications to PEG include conditions such as pharyngeal, esophageal or gastric outlet obstruction or gastroparesis, sepsis, uncorrected coagulopathy or thrombocytopenia. Among the relative contraindications, the presence of oropharyngeal or esophageal malignancy are noteworthy (potential risk of seeding of the PEG tract) (20). The presence of anomalies of the abdominal wall, ascites, hepatomegaly or incisional hernias are also relative contraindications.

PEG is burdened by a low rate of major complications (21, 22), in a percentage of approximately 3% according to the data in the literature (23).

Specifically, such complications may be linked to nutritional factors (diarrhea, delayed gastric emptying, gastroesophageal reflux), mechanical factors (obstruction, rupture, displacement of the system) or factors related to the technique of execution (gastrointestinal bleeding, puncture of adjacent organs, peritonitis, abdominal abscesses, sepsis) (24). In 4-30% of the cases the complications are of the infectious type, ranging

from the infection of the peristomal skin to necrotizing fasciitis. In 3-24% of the major complications peritonitis may develop which in the majority of cases is secondary to the accidental displacement of the PEG with peritoneal contamination. If the displacement occurs soon after the PEG placement, the gastric wall has not yet adhered completely to the abdominal wall and for this reason a chemical type of peritonitis may occur due to the spreading of enteral solution into the abdomen. The seriousness of this complication lies mainly in the fact that often it is diagnosed late with respect to the existence of a neurological disease, severe enough to hinder the early detection of the symptoms and their reporting by the patient. Therefore in patients undergoing a PEG for a neurological disease, it is necessary to follow a strict clinical monitoring in the early stages in order to identify the signs of a suspect abdominal objectivity. Peritonitis may also be connected to the perforation of adjacent cavity organs and in these cases the late diagnosis is often associated to a particularly high mortality rate due to the bacterial contamination of the peritoneal cavity and severe sepsis that results therefrom. This complication, although rare, is closely related to technique errors or to the alteration of the normal anatomical relationships between the stomach and the colon (previous surgery). In other cases, the perforation of the colon may be secondary to an excessive insufflation of the stomach during the endoscopy, which causes a rotation of the stomach, an attraction of the colon upward, resulting in incorrect positioning of the PEG in the colon or in the posterior gastric wall. In a few cases, the accidental injury of the colon may occur with a gastrocolic fistola, manifested with a significant diarrhea. However, the adequate gastric insufflation, the transillumination, the endoscopic view of the needle of the syringe which is performed under local anesthesia, guarantee the correct PEG positioning (25-26).

Given that the treatment is invasive, the execution of the percutaneous endoscopic gastrostomy requires the consent of the beneficiary. However, in the case of an incapable patient, the laws in force in the various European countries appear extremely heterogeneous and one can find different managements with different modalities with which the medical staff have to face the situation where the PEG is proposed as the indicated treatment but the patient is unable to understand the information regarding the treatment and is incapable of providing a valid and conscious consent.

In Italy the PEG, with the exception of rare emergency situations where it is recommended as urgent treatment, inevitably requires the consent of the beneficiary or of the person who is legally representing same, or necessitates the authorization of the tutelary judge, who, endowed with the responsibility and duty to respect the incapable person, may authorize the operation to be carried out. In this way, one momentarily risks positioning the protection of the patient's health second to the attempt to obtain a consent to proceed, without which could be a source of self-responsibility.

In England it is possible to appoint a third party in advance, who, if the patient is unable to decide for himself, consents to the percutaneous endoscopic gastrostomy; moreover, the patient may refuse the PEG operation in advance, provided he is informed about the future consequences deriving from the fact of not undergoing the operation. Indeed, the laws in force in France, Spain and Germany attribute a nullifying value to the advance will of the patient, which must be respected by the medical staff; in addition, also in these countries it is possible to appoint a legal administrator in advance, who, in the interest of the person to be protected and in respect of his will, may consent to medical procedures. In the absence of an advance will and a legal representative, in the case where there is a clear indication for the PEG, the doctor, acting in the interest of the patient and for the protection of same is authorized to consent to the operation. Unlike other European countries, where the regulations appear linear and clear, in Italy the management of the incapable patient appears confused and too ambiguous. The absolute irrelevance of the living will and the impossibility to appoint in advance a Court appointed guardian, places the doctor, in the case of an incapable patient, in a difficult position where a PEG would be clearly indicated, despite the fact that there is no emergency. Paradoxically, in order to avoid running into legal proceedings, the healthcare professional should give preference to the schizophrenic search for a consent rather than defend the good health of the patient, delaying the operation and risking to aggravate his clinical conditions; alternatively, in order to act without a consent,

it would be necessary to wait for a state of necessity and therefore an emergency condition. In this manner, one risks reducing the chances of success of the operation, increasing the possibility of complications.

Conclusions

In conclusion, there are considerable differences in legislation and case law on the management of the PEG with an incapable patient. This situation appears particularly evident in Italy, where an insufficient validity is given to the advance directives or living will. The absence of a unified framework at a European level establishing the issue of medical treatment of incapable patients, results in the fact that, in the different member counties, the self-determination of the patient is respected in different and irregular manners. In fact there is no common interpretation of a fundamental right of a European citizen.

In this sense, for the protection of an equal social status, it would appear necessary for the Council of the European Union to outline some appropriate standards, to be received by all member States, which govern the health management of the incapable patient univocally, both in situations of urgency and/or emergency.

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Correspondence:
Rosario Barranco
Department of Legal Medicine, University of Genova
Via De' Toni 12, 16132 Genova, Italy,
Cell. 3296469335
E-mail: rosario.barranco@libero.it