Part XII

Medico-legal problems and new prospects

Evaluation of Medico-Legal Problems in Critical Lower Limb Ischemia

Giancarlo Umani Ronchi, Giorgio Bolino

Medical-legal aspects related to the treatment of patients with critical lower limb ischemia are mainly centered on issues adherent to the appropriate acquisition of "Informed consent."

Delicate issues are strictly connected to the doctor's professional responsibility. It is clearly evident that importance must be given to correctly informing the patient of the complex clinical condition that often requires a combined approach through different therapeutic applications. Some are particularly invasive while others quite radical to the point of amputation of the limb or section of it.

We are therefore facing an area of prime interest in vascular surgery and operative radiology traditionally known to take a less invasive vascular approach to restore the correct arterial passage. (Fava et al., 2001)

Need for "Informed Consent" during medical proceedings

The consent received during medical proceedings is the leading component for a correct medico-patient relationship. A lack of this acquisition creates a fundamental vice that represents a motive for grave responsibility. Medical-surgical treatment established without respect for one's capacity to choose is illicit and consequently sanctioned not only from a moral and ethical view but also from a legal one.

The basic assumption in the medical-surgical profession is the liberty to cure meaning that the doctor is free to choose his own method of treatment of clinical cases. He will receive complete respect for his knowledge and professional independence. On the medico's part his power to cure is understood to be not only a choice but also an obligation. It is tired to a series of subjective elements (degree, internship, a member of the Medical Association, specialization) and objective elements. The latter particularly refer to the patient's consent. This is the element that perfects the doctor's power to cure. (Iadecola, 2001). One assumes that good health in terms of social relevance is guaranteed after having equally considered the risk factors versus benefits of medical treatment and according to limits that not even the patient's consent can exceed.

At the same rate, one must express the importance of Human Rights and Biomedical Agreements adopted by the European Council of Ministers Committee on November 19, 1996. Art. 5 states:
"An operation on one's health cannot take place until after the person concerned has given free and informed consent".

It is therefore the doctor's precise duty (and not an option) to obtain informed consent. The doctor is also obligated to give complete and thorough information to the patient. The patient's will must be intended as definite and specific to that particular medical treatment and no other.

There is an inevitable passage from an objective and paternalistic medical dimension, where only a competent individual can select and choose what is best for the patient, to a subjective and individualist view that relieves the patient's will from social interests and those of medical science.

In our opinion informing the patient must be seen as an integral and preliminary part of the curing process: in other words it's not a neutral moment but a therapeutic operation. Jung (1981) also expressed his view on this matter "It is not a question of training a patient around what is necessary, but ensuring that the patient is aware of the truth; it is not a question of reaching the patient's mind reaching his heart: when engraving is deep reaction is more effective."

Consent presumes that specific information has been given and this will form the object. The information is supplied by the patient's doctor who will conduct the professional intervention or by a doctor who is delegated on his behalf and is completely aware of the case. The importance of this preliminary advice that will lead to the consent is vital. It is unacceptable that consent can have a juridical bearing (or even an ethical one) without knowing its purpose or its aim.

The Anglo-Saxon phrase "informed consent" is indicative of the correct procedures to follow: first inform, via an adequate conversation, hence obtain a consensus from the patient who is now truly aware. Perhaps, more than information, one should speak of "communication" and stress the need that each doctor presents each argument in a comprehensive manner. Otherwise, the patient's highly decanted "autonomy" is in fact transformed into a hypocritical illusion. The doctor must move in qualitative terms rather than in terms of quantity avoi-

From Critical Lower Limb Ischemia Edited by R Bartolucci, L Battaglia, V D'Andrea, E De Antoni ©2002

ding the comfortable axiom "a lot of information is equal to a lot of consent." The doctor must have a dynamic approach to any therapeutic service on the basis of a common feeling with the patient, a loyal friendship between "un-equals". By taking other measures the doctor will obtain "consensus" but not "consent" from the patient thus creating a medical defensive by way of a legal pretence that can be legally effective but certainly deplorable from an ethical point of view.

The consent must reflect awareness. It must be explicit, legally valid, clear and immune of vices. It must constitute discerning evidence of unobstructed volition for the medical intervention.

Keeping note of the patient's cultural level and of his capacity of discernment, the patient must be informed of the diagnosis, the prognosis, the therapeutic prospective and their consequences and the possibility of alternative therapies. The patient must be placed in a condition where he can decide what opportunity to choose or omit. He will do this by balancing advantages against risks.

All this must be conducted without terrifying the patient and without presenting hypotheses that are absolutely uncustomary, atypical or exceptional complications. One must also avoid superfluous complex precision data of a scientific nature. Obligatory information is extended to predictable risk factors (according to the well know principal "Id quod plerumque accidit") and not to those abnormal fortuitous results. Doctors must be aware that too much unnecessary information could keep patients away even from the most simple operation.

Obligation of information is extended to specific risks as opposed to determined alternatives. With the aid of technical-medical assistance and through a conscientious evaluation of risk versus corresponding advantages, those interested (the patient or his legal representatives) can decide on one choice or the other.

Should the medical-surgical treatment involve a team informed consent must be acquired for each single phase that is being conducted by each doctor who is effectively proposing his own risk factor. Each team member requires results of different instrumental diagnostic tests, each carrying its own significant risk factor for the patient.

The medico-patient relationship must be direct excluding intermediary intervention on the doctor's behalf or relatives on the patient's behalf. Only the patient has the right of responsibility of his own health and cannot delegate others on his own behalf. It is not admissible that family members act as go between or filter medical information unless the patient gives good reason and consensus that permits relative intercession especially when it involves serious therapeutic treatment.

The Voliotion of not Wanting to Know

One's duty to inform may be neglected when the patient or his legal representative clearly expression volition not to know anything regarding the clinical condition that requires particular medical attention, therefore relying totally on the doctor. In this case it is not legally necessary, nor logical, to insist on giving information or explanation because consent is a patient's right and not a question of duty. (Comma 2, Art.10 of the European Convention on Human Rights and Biomedicine states: "when a person's volition is not to be informed this volition must be respected"). Therefore, the patient's wish must be respected and consequently trust in the doctor is considered implicit. This trust is clearly temporary and valid until the patient decides to resume power of decision. We feel that it is indispensable in these cases, that the doctor accurately documents in detail the volition of the patient or that of the patient's legal representative.

Medical Practice Objectors and Relevant Living Will Directives

Particular cases may involve people who are incapacitated or in a state of unconsciousness. These may bring with them explicit declarations "living wills" or "biological wills" of dissent towards every kind of therapeutic treatment or towards any specific type of therapeutic treatment that could even be considered indispensable to avoid death (e.g. blood transfusions in the case of Jehovah Witnesses). In our opinion these living wills are best described under a legal profile so that the doctor's actions are transparent hence avoiding on one hand the possibility that subjective rights become debatable and on the other that possible negative charges be used against a doctor who has chosen to take determinate therapeutic action.

In these cases, it is necessary to emphasize the possibility of offering an alternative therapeutic approach as opposed to the method that ferments objection. This is acknowledged in the Code of Conduct and Surgical Treatment of Jehovah Witnesses drawn up in 1996 by The Royal College of Surgeons of England. In relation to the therapeutic treatment to be practiced two possibilities must be taken into particular consideration. These regard the concept of actual consent:

a) the patient has not expressed volition before losing consciousness. In this case the doctor will exclusively make reference to the actual state of necessity that exists and on the basis of his duty to lend emergency aid acting absolutely in the best interest of the patient's health and never considering opinions or decisions expressed by family members;

b) the patient, before losing consciousness, has expressed a precise and documented volition dissenting from medical practice. In this case two different positions must be examined:
   i) the patient is in a state of unconsciousness or incapacitated but the condition is considered predictable and expected, since it is the natural evolution of a particular malady, so dissent against therapeutic treatment was expressed (e.g. Jehovah witnesses refuse blood transfusions when they are subject to surgery where blood transfusion can be necessary). This is a delicate equilibrium between personal rights and medical assurance for a patient that has been assigned to a medical practitioner by society and for which collusion in suicide is unacceptable. In this case what prevails is the hypothesis of the patient's volition actually expressed through informed dissent. Art 9 of the European Convention on Human Rights and Biomedicine states: "Volition, previously expressed by a patient regarding surgery but subsequently incapacitated from expressing volition at the surgical moment, will be kept in consideration".
   ii) A patient is unconscious or incapacitated due to an unforeseeable or unpredictable accident but had expressed dissent towards a particular therapeutic treatment which is outside any strict adherence to the urgent clinical condition (e.g. Jehovah Witnesses who carry a declaration refusing blood transfusions and are in a state of unconsciousness following an accident that is urgently in need of a blood transfusion); consent can be considered as "presumed" because if it is true that informed consent is valid only after giving detailed information adherence to each concrete case, it is also true that informed dissent is can also be validly expressed not in preventive or hypothetical cases but only when actual surgical intervention arises; even though a living is not recognized as having an absolute and binding juridical value, the doctor should however, keep in consideration the volition expressed by the patient in the past and evaluate the effectiveness of an alternative therapy.

As far as a minor is concerned and while not in any condition of necessity, jurisprudence has sanctioned that the right to one's health has to be protected even against the parents will. Recourse is sort from the judge because one cannot presume that a minor is totally convinced of religious values prevailing above the values of life and health.

Consent to Surgery

It is opportune that consent be expressed in the case of a precise surgical intervention, giving the doctor mandate (or not) to modify the surgical technique according to the requirements of the case and as they unfold during the operation. The patient's volition must therefore be very clear. This mandate is maintained within certain limits, because of surgical changes that can lead to higher surgical risk, such as removal of organs, amputation or the predictable and significant rise in functional deficiency.

Dealing with a "broadened" consent means being generically exposed to the unpredictable. This can be interpreted as a choice of unawareness. A broadened consent will permit the surgeon to adapt his surgery to the different clinical-therapeutic circumstances that come about during the operation but it can be inconsistent with the patient's original volition or that of the patient's legal representative. Therefore, respect for specific and explicit consent brings us back to the patient and the need to be able to express one's will.

In pediatric cases the problem is less relevant because generally one simply suspends the operation rather than interrupt it. One re-establishes a dialogue with those who have legal custody over the minor to discuss changes and unexpected needs. The European Convention for Human Rights and Biomedicine stresses the importance of authorization by the legal representatives and also accentuate the fact that "according to the minors age and level of maturity the minors opinion is taken into consideration and plays a determinate role" (art 6, para 2).

Consent by the Elderly and Mentally Disabled

Critical ischemia of the inferior limbs is a pathological condition often connected with degenerative and arteriosclerosis factors, which in most cases affect elderly patients and those mentally, disabled.

Decision making capability is not a phenomenon of "all or nothing". It needs to be discussed and then compared to different cases that can be either simple or complex. At this point the patient can be lead to autonomously exercise right of choice. Furthermore, in a progressively growing trend that stabilizes and then decreases, one finds that the cognitive capacity passes through different phases of life that correspond equally to different decision making capabilities. This is applicable not only to minors but also to elderly patients and those mentally infirm.

Geriatric consent is becoming a pressing modern day issue due to the common problems that affect the Western world such as low birth rate and demographic longevity. The question is can we be satisfied at all costs with the consent that is expressed by elderly patients. It is a fact that the frequent impoverished cognitive aspects connected with old age, show that decision-making is substantially open to evaluation from an ethical point of view even though decision making by the elderly is valid from a legal prospective.

The same considerations apply for cases of dementia such as Alzheimer, or generally speaking, cerebral deterioration and senile decay of psychic functions.

In the case of a minor, the parents are automatically considered legal representatives to whom requisition and acquisition of informed consent is made. As for the elderly who are mentally incapacitated but not assigned to legal guardianship, they remain the only people who can legitimately receive information and who in turn can express consent for the medical intervention. Contrary to what takes place in pediatrics, where there is a presumption of incapacitated decision making. In geriatrics there is a juridical presumption (dubious under an ethical profile) of decision-making capacity (to all'exitus) unless measures of interdiction are taken. Clinical cases and realistic terms show that being of sound mind is often compromised in elderly people especially in relation to complex cases.

Important indications by the European Convention on Human Rights and Biomedicine are of no help, as they only recommend the necessity to obtain consent from the legal representative for those cases in which, according to the law, the adult has lost the ability to give consent "due to mental handicap, due to illness or similar reasons. The person concerned, must be involved in the procedure for authorization when possible" (Art. 6). Nothing is mentioned in relation to cases where people are not sound of mind but haven't been legally recognized as such.

In a practical sense, it is our opinion to:

1) action precocious diagnosis in order to immediately orientate the person towards precise future volition regarding foreseeable clinical therapy and assistance even if this means use of living will directives;
2) gradually and progressively carry out therapeutic treatment in such a manner as to lead the patient towards a gradual improvement in recognizing the disease together with a better decision making ability: have the patient in condition to face the most complex therapeutic and/or surgical profiles;
3) involve the elderly and the mentally disabled as much as possible in decision-making processes together with the families; professional secrecy must be stressed as well as the exclusion of decision-making by the families on a juridical and ethical level (advanced directives could consent to the possibility of effectively involving the families);
4) request the judge to intervene, as is the case with minors;
5) involve the ethics committee so as to acquire guidelines for conduct referral.

Consent therefore becomes the "objective" of the therapeutic report (through "minor consents" = consent in progress). Under the doctor's guidance even elderly or mentally infirm patient must become "competent" in making responsible choices in a therapeutic relationship "progressively" built in doctor-patient "collaborating talks".

Advance Health Care Planning is now a pressing argument expressed in writing in living wills and which has existed for years in the USA (Singer et Siegler, 1992; Alpers et Lo, 1994). Doctor-Patient communication is promoted, the patient is highly involved, there is respect for personal autonomy, and reassurance is offered to spouses regarding the correctness of the cure in relation to the patient's volition (Lorè et al., 2000).

Method, Documentation for Consent (o Dissent) and Relevant Forms

The patient's consent is generally intended as explicit consent. Implicit consent must be limited to routine diagnostic-therapeutic cases, without life threatening risks for the patient. Presumed consent is viewed in cases in which the patient lies in a state of permanent o transitory psychic incapability and presents such a health condition that could lead to actual danger of serious damage to the person. It is also viewed in relation to a clear state of necessity and always when the medical intervention is proportional to the risk.

Apart from the few exceptions, consent must not be presumed, nor implicit, even less so generic or broadened. It must be explicit and aimed at particular treatment that has been previously agreed upon.

Referring to the previously mentioned exceptions it is useful to return on the subject of "state of necessity" (regularized in Italy according to Art. 54 of the criminal code) where formative duty and hence the necessity to acquire consent, does not recur. This leads to extreme situations in which the medical operation, no matter what the result may be, reveals itself as necessary and urgent and the patient is not in condition to express conscious volition be it favorable or contrary. In these conditions the medico may act in the absence of an explicit consent as quoted in the European Convention for Human Rights and Biomedicine (Art.8) "When found in an urgent situation, and the appropriate consent is

unobtainable, one can immediately proceed with any medical surgery that is indispensable for the well being of the person concerned".

Consent, and even more so, dissent towards a medical intervention should in our opinion be amply documented, especially when treatment incurs risk or is susceptible to danger for the patient.

Regarding this matter it should be noted that Italian law does not provide a form in which consent can be expressed. This means that even an oral "form" is regarded as valid. We recommend that doctors and institutes that practice informed consent obtain consent in writing (in the presence of a witness) and keep it together with patients medical history file. An audio or video recording could also be of benefit during the doctor's conversation with the patient.

We cannot stigmatize the conduct of those doctors or Institutes that rush through this delicate procedure of consent by requesting a patient to simply sign a printed form that contains extremely generic information, without any personal details. This type of consent is clearly not valid under any moral, ethical and above all juridical profile.

On the other hand, overly precise and "politically correct" forms that give consent to the most disparate surgical objectives overcome false problems. The forms assume the appearance of presumptuous and hysterical "terms and conditions of tender" (Fiori, 1999) supported by information that is meticulous but at the same time catastrophic, obviously utopian considering an infinity of different patients and the specific pathological scenes. All this evidently in the distort conviction that one is protected from every angel in the event of professional liability.

In this case the best proposal is paradoxically a "non-form". The paradox is more hypothetical than real considering that the root of the word consent is indicative of "listening together" in a therapeutic alliance that requires information but more so "talk" and "empathy" with the patient.

This conviction does not contrast with the informed consent (or dissent) forms often mentioned in literature and we propose the following template that is most useful when treating critical ischemia of the inferior limbs and in cases of surgical amputation. It deals with operation indications that can help mnemonic procedures thanks to sufficiently comprehensive questions regarding all the indispensable elements of a juridical and medical-legal nature. At the same time it is elastic in a way that permits opportune and responsible adaptation to each particular case. Obviously one hopes that the sections filled in by hand are always preponderant. It should reflect the inseparable binomial medico-patient of a single and unrepeatable concrete case.

During the phase of acquisition of consent, the presence of a witness is recommended. It is preferable to choose a witness amongst persons who are obligated to respect professional secrecy but this is at the patient's discretion and according to his indication. Anyone may be called to fill this role.

POSSIBLE FORM FOR INFORMED CONSENT (OR DISSENT)
WITH PARTICULAR REFERENCE TO THE
TREATMENT OF CRITICAL ISCHEMIA OF THE INFERIOR LIMBS

I, the undersigned, born on _____ in _____
Declare to have been amply informed on the nature, evolution and every predictable complication of the infirmity of which I am effected and more precisely _____

As well as the following therapeutic treatment offered by today's modern science with the relevant indications and counter indications:_____

I have been informed in detail of the clinical and instrumental tests that have to take place and the possible use of contrast substances and/or invasive techniques and methods for diagnostic therapy and that is

I am aware of the generic risks related to the technique and the methodology to be used. It has been explained clearly and comprehensively. Particular attention has been paid to the type of medical-surgical intervention. It has been chosen in common accord with the surgeon after an attentive examination of advantages and disadvantages, relevant techniques applicable, the possible complications that could derive from this operation even though it has been conducted scrupulously, with diligence and precision._____

In addition I have been informed that my general condition of health expose me to the following added complications, _____

Therefore, I consent to the medical act/surgical intervention and the relevant technicalities explained to me as follows:_____

I also accept that the surgeon modifies the operation technique and the type of operation agreed upon should this be necessary during the course medical-surgical act and only if this surgical change does not mean an increase of the operative risk, removal of organs, amputation or the introduction of a significant functional deficiency.

OR

I dissent to the medical-surgical act that has been proposed to me as follows:_____

The patient confirms in writing that he has been adequately informed and accepts or declines.

Date:_____

Patient's signature_____
Signature of parent or guardian_____
(In the case of a minor or mentally disable)

Signature of Doctor responsible for the medical-surgical act_____

Signature of Witness_____

POSSIBLE FORM FOR INFORMED CONSENT (OR DISSENT)
WITH PARTICULAR REFERENCE TO THE AMPUTATION IN THE
TREATMENT OF CRITICAL ISCHEMIA OF THE INFERIOR LIMBS

I, the undersigned, born on in Declare to have been amply informed on the nature, evolution and every predictable complication of the infirmity of which I am affected: _____

As well as the following therapeutic treatment offered by today's modern science _____

I have been informed in detail of the necessity to amputate the inferior limb (Dx/Sx) at the following level_____
And of the consequences of the amputating operation and the possible application of a prosthesis and ulterior operations, of the cost, its duration and the effectiveness of the prosthesis itself.

I am aware of the generic risks related to the technique and the methodology to be used. It has been explained clearly and comprehensively. Particular attention has been paid to the type of medical-surgical intervention. It has been chosen in common accord with the surgeon after an attentive examination of: advantages and disadvantages; the relevant techniques applicable; the possible complications that could derive from this operation even though it has been conducted scrupulously, with diligence and precision:_____

In addition I have been informed that my general condition of health expose me to the following added Complications,_____

Therefore, I consent to the medical act/surgical intervention and the relevant technicalities explained to me as follows, _____

I also accept that the surgeon modifies the operation technique and the type of operation agreed upon should this be necessary during the course medical-surgical act modifying the level of amputation that had been proposed to me.

OR

I dissent to the medical-surgical act that has been proposed to me as follows: _____

The patient confirms in writing that he has been adequately informed and accepts or declines.

Date:_____

Patient's signature_____
Signature of parent or guardian_____
(in the case of a minor or mentally disable)

Signature of Doctor responsible for the medical-surgical act_____

Signature of Witness_____

Conclusive Considerations

It has been said that consent to medical intervention constitutes the baring element of a correct medico-patient relationship; In the same manner the medico-patient relationship that is not based on informed consent of the medical intervention is considered flawed and this determines important responsibilities (criminal, civil, administrative and disciplinary)

Even though these considerations are well known, they are often seen as unbearable by doctors together with other medical-legal aspects of the medical profession. They are judged as a sort of bureaucratic annoyance that has to be dealt with as quickly as possible when one can't avoid them.

This comes from,
1. lack of medical-legal training as part of one's curriculum;
2. lack of or no consultancy within the heath institute by the medical-legal specializing institutions;
3. an obsolete cultural heritage that nonetheless still survives in some elderly medical professionals: these supreme medical guardians of health, gifted with charisma, inalienable with undisputable decisive power over the patient.

The hypothesis of professional liability is escalating due to these three factors and it is clearly visible in the Italian health service.

Doctors should pay more attention to the meaning consent if not for any other reason at least to protect their professional profile. The crisis that is undoubtedly affecting the medico-patient relationship stems from the fact that doctors today concentrate more on the disease and less on the patient. From our experience many are the cases of presumed professional liability. Empathy towards the patient and the family is scarce and this generates retaliation that could be avoided.

Doctors are pressing for defensive medicine. Defensive medicine takes place when doctors prescribe tests, treatment or visits (active defensive medicine) or avoid patients or high-risk treatment (passive defensive medicine) solely, for the purpose of reducing the risk of professional liability. The weight of the medical decision is referred to others rather than the doctor: the patient, family members, ethics committees and magistrates.

Doctors who don't want to lose professional credibility must pass on to others decisions that are not of their competence. This should protect the patient's rights rather than be a comfortable means of diminishing the doctor's sphere of responsibility/liability.

Passive defensive medicine appears somewhat dangerous for the medico in as much as it opens the hypothesis of professional liability known as "omission." (Barni, 1995I-II).

Finally, from euphoria "in dubio pro reo" there is a certain risk of passing to "in dubio contra medicum"

(Crespi, 1992) in light of the rigorous rules of good conduct for doctors more than for the common citizen or other professional categories. This eliminates the prejudice that the medical profession is characterized by responsibility that is simply relative.

Last but not least, it must be clearly evident that the acquisition of consent from a patient is not a ruling antidote since it does not exempt the doctor from 1) informing the patient correctly; and above all 2) it doesn't exempt the doctor from possible professional liability (Neisel et Kuczewski, 1996). The acquisition of informed consent, even if correct, does not annul the verification of the defect whether is be generic (negligence, imprudence, inexperience) or specific (unobservant of the law, regulations, orders or discipline).

REFERENCES

(1) Alpers A, Lo B. *Advance planning for advance directives.* J. Gen. Intern. Med., 9, 593, 1994.

(2) Barni M. *Il rapporto di causalità materiale in medicina legale.* Giuffrè, Milano, 1995[I].

(3) Barni M. *Dalla valorizzazione scientifica alla vaporizzazione giurisprudenziale del nesso causale.* Riv. It. Med. Leg., 17, 1021, 1995[II].

(4) Barni M. *Diritti-doveri, responsabilità del medico. Dalla bioetica al biodiritto.* Giuffrè, Milano, 1999.

(5) Battaglino F, Ravaioli A. *Consenso informato nell'attività medico terapeutica.* Fed. Med., 10, 36, 1993.

(6) Bilancetti M. *La responsabilità penale e civile del medico.* CEDAM, Padova, 1998.

(7) Bolino G, Bonaccorso L. *Argomenti di medicina legale in pediatria.* Mediserve, Firenze-Napoli, 1998.

(8) Crespi A. *I recenti orientamenti giurisprudenziali nell'accertamento della responsabilità professionale del medico chirurgo: evoluzione o involuzione?* Riv. It. Med. Leg., 14, 785, 1992.

(9) De Caprio L, Prodomo R, Ricci P, De Palma A, Bove A. *Consenso informato e decadimento cognitivo.* Riv. It. Med. Leg., 20, 901, 1998.

(10) Fava C, Grosso M, Veltri A, Rabbia C. *La radiologia interventistica nel ripristino della corretta canalizzazione arteriosa.* Professione, sanità pubblica e medicina pratica, 9, 40, 2001.

(11) Fineschi V. *Il rapporto medico-paziente: consenso, informazione e segreto.* In Giusti G.: Trattato di medicina legale e scienze affini. CEDAM, Padova, 1998, vol. I, pag. 494.

(12) Fiori A. *Medicina legale della responsabilità medica.* Giuffrè, Milano, 1999, vol. I.

(13) Fiori A, La Monaca G. *L'informazione al paziente ai fini del consenso: senza più limiti.* Riv. It. Med. Leg., 22, 1302, 2000.

(14) Freni F. *Biogiuridica e pluralismo etico-religioso.* Giuffrè, Milano, 2000.

(15) Fucci S. *Informazione e consenso nel rapporto medico-paziente. Profili deontologici e giuridici.* Masson, Milano, 1996.

(16) Fucci S. *Il consenso informato nel mirino del legislatore.* Professione, sanità pubblica e medicina pratica, 4, 60, 1996.

(17) Iadecola G. *Potestà di curare e consenso del paziente.* CEDAM, Padova, 1998.

(18) Iadecola G. *In tema di rilevanza penale – come delitto doloso contro la vita e l'incolumità individuale – del trattamento medico eseguito senza il consenso del paziente.* Riv. It. Med. Leg., 23, 219, 2001.

(19) Jung C G. *L'applicabilità pratica dell'analisi dei sogni.* Opere. Boringhieri, Torino, 1981, vol. 16, 149.

(20) Lorè C, Del Grosso M, Cecioni R. *Personalizzazione delle cure e coinvolgimento nelle decisioni cliniche: note sulla advance health care planning.* Riv. It. Med. Leg., 22, 709, 2000.

(21) Meisel A, Kuczewski M. *Legal and ethical myths about informed consent.* Arch. Intern. Med., 156, 2521, 1996.

(22) Santosuosso A. *Il rapporto medico paziente nel diritto e nella giurisprudenza.* In AA.VV.: *Guida all'esercizio professionale per i Medici Chirurghi e gli Odontoiatri.* Edizioni Medico Scientifiche, Torino, 1994.

(23) Santosuosso A. *La ricerca clinica nei soggetti non capaci.* Professione, sanità pubblica e medicina pratica, 6, 41, 1998.

(24) Singer P A, Siegler M. *Advancing the cause of advance directives.* Arch. Intern. Med., 152, 22, 1992.

(25) Umani Ronchi G. *Il consenso all'operazione deve essere esplicito e non filtrato dalla mediazione dei familiari.* Guida al diritto-Il Sole 24 ore, 8.2.97, 4, 67, n. 5.

Telemedicine and Critical Lower Limb Ischemia

Sergio Pillon

What is the meaning of Telemedicine?

Litterary and "historically" it is the transmission of medical data, but now it means also all those applications that permit to the doctor through some transmission system of being near his patient, the technitian or near of his colleague.

The simplest and more used system from its invention is the telephone, that is still used to assist patients on ships or planes, but the computer has extended enormously the possibility adding images and data transmission.

Another boost has been produced by Internet diffusion, keeping at one's disposal a low cost standard for data transmission, a total diffusion all over the world, until the outlying zones.

Today it should be better thinking the Telemedicine as a guarantee of a high qualified assistance in every places where it shouldn't be possible or cheap in neurosurgical, angiological, cardiovascular or dermatological emergencies.

From the patient's point of view, the Telemedicine is the instrument for eluding patients' movements, sending only informations.

Today, for example, the patient's iter in Italy is: he has a written application from his personal doctor, with this application he goes to the hospital and thus he have the date of checkup, he comes back to the hospital for the examination and then he has to return to his personal doctor.

In all this iter, the patient has to be present only during the personal doctor's examination at the hospital checkup.

On the contrary, during a travel it's the telematic system that permits the reservation, the ticket, the withdrawal and the payment.

Thus, the passenger has only to travel and he hasn't to obtain the relative documents.

Today Internet simplifies everythings, so the Telemedicine has to leave the research laboratories and come into daily recurrence.

Scenary of vascular teleconsultation

From 1985, I deal in Telemedicine for the Italian Antartic exploration program (Research Antartic National Program, PNRA) with the Experimental Institute of Medicine of CNR (National Council of Research), directed by Professor G. Ravagnan, one of the founders of the italian Telemedicine.

In 1989 we have presented to italian Nobel prizes the first CNR prototype system of Telemedicine, realised with the BIOTRONIX company of Rome, and we have been invited to present our researches to the Royal Academy of Sweden in 1996.

In 1990, San Camillo Hospital of Rome has taken part in the project with the Angiological Division and from 1992 we deal in Telemedicine researches about the CNR project "Everest K2", from the pyramid built on the botton of Mount Everest.

Nowaday, thanks to the great quantity of dates and realised experiences, we can summarize the possible scenaries of vascular teleconsultation based on telematic technologies:

1. Local or remote collection between a centre with not expert doctors in vascular field and a centre with vascular specialistic competences (first opinion).
   In this case we adopt recorded teleconsultations solutions (that is images and examination' data transmission in advance on the real consultation). Generally, the results time isn't critical, except for emergency cases for which it could be necessary the audio-video connection (in this case we speak about "live" teleconsultation).
2. Remote connection of a first level vascular centre with an other one of high specialization, for having an opinion (second opinion), connected in particular complex cases. Generally, the more adapted and frequent type of connection is the recorded teleconsultation.
3. Local and remote connection of a vascular centre with a specialistic and medical centre, even if it isn't a vascular centre, for an opinion about an emergency case (f. e. indication for an amputation or a therapy).
   In this case, the more adapted connection is, evidently, the audio-video one (live consultation).

Consequently, it's possible to focalize two principal "models" of vascular teleconsultation: the recorded teleconsultation (off-line) and the live teleconsultation (on-line).

From Critical Lower Limb Ischemia Edited by R Bartolucci, L Battaglia, V D'Andrea, E De Antoni ©2002

In the recorded teleconsultation, the diagnostic process forsees the following passages:
- connection
- images and patient's data research and selection to send to the centre in which the consulence is requested.
- teleconsultation request's sending and images and patient's dates transmission from the requesting part of the centre.
- case's exam from the consulted centre
- result's sending (not necessary as a formal report but such as an opinion) from the consulted centre.

In the "live" teleconsultation the process is partially different:
- appointment for the connection
- connection
- images and patient's dates research and selection to send to the centre in which the consulence is requested
- preliminar images and patient's dates sending from the requesting centre
- audio-video discussion with the simultaneous management of the events on both stations (requesting and consulted). This operative process is generally called "shared whiteboard" (SW) and it represents the highest level of medical cooperative work.

Realized experiences

The medium length of a teleconsultation session, during the experimental prooves, is about of 25 minutes.

This length is connected in the experimental scenary of the model, for the material's exam (patological and uncertain description, "border line" cases, rare disease...).

In different scenaries, it could be possible to suppose that the medium times of the sessions reduce considerably.

The work of the operators, for both places is obviously in proportion to the recorded length for the session: we have obtained values as 55 minutes for the doctors and 45 minutes for the technics.

Compared with the direct and hard work of the operators, the teleconsultation introduction involves from the other side important modification in the diagnostic process and in the results (costs, efficiency, diagnostic quality, customer's comfort).

It has been used a conceptual model for analyzing the different aspects of its impact, in which it has been considered these metodological elements:
- process time: sessions' length, operators' work...
- cost of technologies (communications, equipment...), formation, transport (operator, patients)
- economic and time saving for the patient
- diagnostic confidence
- improving of services' images
- diagnosis' time

It has been compared the two scenaries with/without telematic help of technologies for the valuation.

In this way, it has been possible to analyze the different ways of technologies use and confirm the real points of force and the conditions of a real convenience, efficiency and benefits.

Operative suggestions

Organization of sanitary company

The telemedicine system has to be CENTRAL in the sanitary centre.

It's surely a time and resources loosing to realize systems dedicated to the single specialization and patologies.

The dates network, the technologies are substantially the same, changes a little the interfaces of instruments.

It's a part of data network's centre, that it has to be integrated with the voice network (telephone).

All this doesn't mean that every specialization has to execute the telemedicine in a dedicated ambient, the digital data can be sended everywhere in the centre data network, but the coordination has to be unique for the centre for reducing the costs of technologies and for increasing the benefits.

Typologie of the teleconsultation

Nowadays a great number of the experiences involves the emergency.

The emergency is complex, it request a lot of time and resources and moreover it is always a teleconsultation on line.

The best way for starting it's the consulence, results within the following 24 hours (off-line teleconsultation). The costs are lower and they permit of doing experience and replying to the most part of the scenaries, to the patients' need, given a contribution to the staff's formation and to the technologies experiment.

Medical/Nursing organization of the diagnostic service

The teleconsultation has to be "low invasive" for the doctor's, the technic's or the nurse's point of view.

It's necessary to define correctly the modulistic of the requests' sending, the results' commitment and their archives, the technic staff of support.

The diagnostic medical procedures has been tested since ten years or centuries of practice.

The teleconsultation has to be studied with attention for optimizing the processes.

Security

The related problems interest the informatics more than doctors.

The reality of the digital firm in Italy interest the doctor and the legal value of the documents.

The privacy interest the patient, he can obtain it with the actual technologies of VPN (private virtual network) and transmission protocols for guaranting all that involves the actual legislation.

The networks of public dates transmission: characteristics, forces and weakness point

Telematic fixed network

Telematic connection among earth's stations.

The connection is based on STRUCTURE DATES and VOICE offered by the local Telecom or other Internet provider.

The technologic standard offered on the market by telephone providers to the companies, with the additional systems for guaranting the privacy, is substantially similar and it offers a large possibility of choice.

The communication protocol is the standard one of Internet, the TCP/IP available in all the operative systems, with VPN systems (private virtual networks, PPTP).

The most important connection possibilities are:

1. Dial up
   The connection is activated when it's necessary, as a common phone call.
   It's possible to use the normal telephone line, or an ISDN line.
   The connection through the phone line permits a slow videoconference, the dates, fixed images, plans and RX exams sending.
   Costs: from 100.00 Euro to 500.00 Euro for a year, plus phone cost (about 1.00 Euro, 2.50 Euro for 1 hour).
   Benefits: installation's semplicity, low cost of exercise.
   Disadvantages: limits and slowness of the plans and complex images' transmission
2. Fixed dates line
   Using Internet connections for the companies from ADSL to XDSL until the lines dedicated called "point to point" (CDN), very expensive but with very high security.
   Costs: from 500.00 Euro to 6000.00 Euro for a year, without an additional cost for the phone increments.
   Benefits: active connection 24/24 hour, transmission speed, also for plans and complex images and videoconference.
   Disadvantages: costs, moreover justified by the benefits.

Mobile telematic network of first level

Mobile and moving instruments but however connected with the fixed and mobile phone.

The possibility of phone connection permits two hypothesis before described:
DIAL UP (normal phone connection) and
DATES LINE using technologies with GPRS or UMTS

Mobile telematic network of second level (satellite)

The network has to transmit dates, plans and images from the territory and in absence of a fixed network.

The instruments has to connect to the satellite network of support.

The inauguration of the satellite networks from 1998 has permitted the commerce of cellular phones DUAL MODE, adding GSM-satellite technologies, GSM 1800 satellite, GSM 1900 satellite, AMPS satellite...

These terminals are able to change automatically on the satellite network when it's doesn't more exist the radio cellular earth's network.

In fact, nowadays even if the earth cellular systems increase, are not able to cover all the earth and so it's necessary the action of the radiomobile satellite networks that permit the communications with remote areas all over the world.

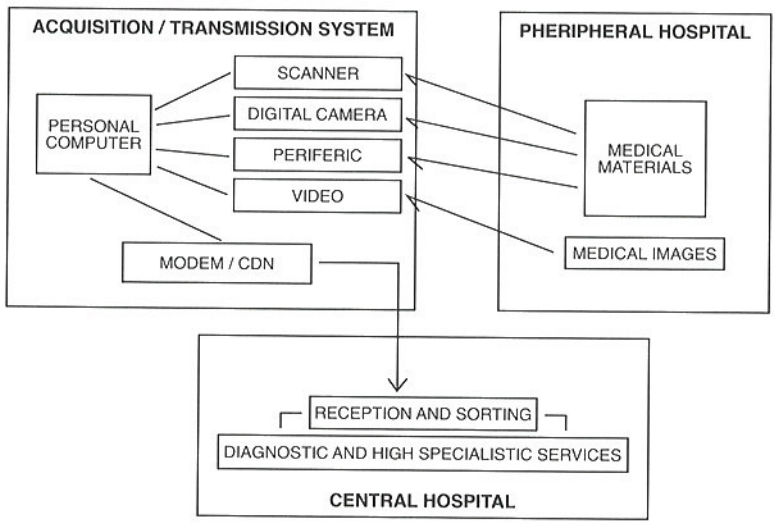

FIGURE 1
Telemedicine system

REFERENCES

(1) LEVINE SR, GORMAN M. *"Telestroke" : the application of telemedicine for stroke.* Stroke (United States), Feb 1999, 30(2) p464-9.

(2) LUGG DJ. *Telemedicine: have technological advances improved health care to remote Antarctic populations?* J Int J Circumpolar Health, 57 Suppl 1():682-5 1998.

(3) WRIGHT D. *Telemedicine and developing countries. A report of study group 2 of the ITU Development Sector.* J Telemed Telecare, 4 Suppl 2():1-85 1998.

(4) TAYLOR P. *A survey of research in telemedicine. 1: Telemedicine systems.* J Telemed Telecare, 4(1):1-17 1998.

(5) WIRTHLIN DJ, BURADAGUNTA S, EDWARDS RA, ET AL. *Telemedicine in vascular surgery: feasibility of digital imaging for remote management of wounds.* J Vasc Surg (United States), Jun 1998, 27(6) p1089-99; discussion 1099-100.

(6) AUCAR JA, DOARN CR, SARGSYAN A, ET AL. *Use of the Internet for long-term clinical follow-up.* Telemed J (United States), Winter 1998, 4(4) p371-4

(7) MAIRINGER T; GABL C; DERWAN P; MIKUZ G; FERRER-ROCA O. *What do physicians think of telemedicine? A survey in different European regions. J Telemed Telecare, 2(1):50-6 1996.*

(8) ELFORD DR. *Telemedicine in northern Norway.* J Telemed Telecare, 3(1):1-22 1997.

(9) HASTON W; HORSLEY H; MILNE A. *Establishing a postgraduate qualification in remote health care.* J Telemed Telecare, 2(2):114-8 1996.