Medico-legal viewpoints of interventional ultrasonography

MEDICO-LEGAL VIEWPOINTS OF INTERVENTIONAL ULTRASONOGRAPHY

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As a modern diagnostic and therapeutic procedure, interventional ultrasonography must be an alternative offer to patients compared with traditional techniques, after having considered the priority of risk-benefit balance and not neglecting the cost-benefit relationship which is essential for the National Health Service.

On the one hand this new technique reduces but doesn't exclude any risk of invasive surgery, but on the other hand it narrows the margin of error in comparison to traditional surgery. For these reasons it cannot be considered an easy technique, and must be performed by technically skilled or adequately advised physicians, in medical centres sufficiently equipped on the basis of the knowledge and experience of the operators; close co-operation with other clinical units, particularly with a surgical unit, should be arranged, so as to counteract any complicating disease and accomplish a better management of the patient, achieving also a possible mutual learning [1].

The medico-legal subjects of medical responsibility and informed consent, despite the fact that they are common to the doctor-patient relationship, have in this particular field aspects of particular interest, and will be thus discussed subsequently.

THE MEDICAL LIABILITY

It is based upon the contextual presence of the three classical elements: *professional malpractice, damage* to the patient, the proof of the *causal connection* between the one and the other.

Not every *error* implies the existence of liability but only the censurable one, thus excluding the casual one, originated by shortcomings of science or by situations beyond the real possibility of control by the doctor. The doctor is to be considered guilty for an action or omission, expression of lack of diligence, prudence or skill, or if he doesn't follow law, rules, orders or disciplines, according to the Italian Criminal Code (art. 43).

Negligent behaviour is that which shows carelessness (this, in any case, could be excused if framed in a situation of tiredness or of stress during a frantic forced activity), but above all heedlessness, superficiality and insensibility towards the needs of the patient. Behaviour can be called *imprudent* when it implies excessive risk, putting the safety of the patient in danger and without opportune risk-benefit balance. The doctor, even if he is able to foresee and prevent the danger, runs a risk in any case and is guilty of imprudent behaviour. *Unskilled* behaviour is that which lacks specific preparation, ability and experience. Inexperience must be evaluated in relationship to the rank of the physician, in that much more will be expected of a specialist or of a physician in a high position [2]. A doctor cannot be considered unskilled simply if he does not carry out the best diagnostic or therapeutic technique, but only if he shows a degree of skill and learning below that ordinarily possessed by the majority of the members of his profession of equal qualification or specialization.

Failure to comply with norms could apply to service regulations arranged by the head

of the structure (such as the sanitary manager, the head physician or the assistant physician). It brings about the existence of a "specific fault", in itself liable to disciplinary prosecution, and that is the cause of a major liability in case of damage to the patient; i.e. disrespect for schedules or shifts, eventual protocols established for specific operations, as, for example, interventional US.
In this specific case various aspects of *guilt* for the error can be hypothesized and identified.

• Operation *advice.* If it is possible to prove that interventional US was replaceable with other less or non invasive techniques, appropriate to obtaining the same diagnostic result; or when other traditional surgical procedures, safer and effective in specific cases, were neglected unreasonably (for example, in the treatment and in the draining of abscesses or haemorrhages); and furthermore when another safer and more accurate interventional radiological technique could be used, i.e. guided CT, in these cases the behaviour would emerge as clearly imprudent.
It must be considered that advice for operation could come from many kinds of physicians, both within and outside the hospital, but this does not exempt the operator from the obligation of attentive *verification*, omission of which would determine negligent or imprudent behaviour. He cannot, in fact, be considered only a material performer, but a specialist able to decide for the patient, after having considered the advantages and the difficulties of the operation.
• The evaluation of *contraindications.* The following acts can be examples of imprudence and/or negligence: a missing anamnesis concerning risk conditions, particularly of bleeding (haemorrhagic states, drug intake interfering with haemostatic processes, as the common aspirin); a failure to check laboratory results regarding haemocoagulation; an imprudent biopsy targeted at lesions prone to haemorrhagic risk (angiomas, hemangioendothelioma, and high vascularizated tumors) or an inappropriate manoeuvre in conditions of risk, for example, of intestinal perforation. The verification of contraindications also cannot be delegated by the operator.

• The *choice* and *control* of *instruments.* It is the responsibility of the interventional US operator to choose the right needle, according to balanced requirements of safety and result. The control of operation instruments, even if entrusted to nurses or technicians, is always the duty of the physician and, in hospital, of the chief physician who is officially obliged to signal possible ineffectiveness to the sanitary direction also. Inadequate behaviour in these situations could constitute imprudence, negligence and/or incompetence.

• Operation *procedure.* An unwise or unskilled manoeuvre may be related to the fact that the approach was ill-judged with regard to the aims, with a target error due to wrong interpretation of the echographic image, with an unjustified repetition of penetration in the lesion and in the tissues, with the targeting of the biopsy needle towards high risk pathologies (i.e. risk of haemorrhage or of perforation).

• *Lack of preparation* in facings *complicating diseases.* Failure to make a prognosis or a technical and instrumental inadequacy could constitute negligence, imprudence or incompetence in a complicating situation. The hypotheses for error can be exemplified as follows: in a reduction of due waiting and control times of the patient after ambulatory or day-hospital operations; in a failure to make a prior check of blood group type in cases of risk of haemorrhage; in a neglected antibiotic covering in front of the

risk of a provoked intestinal perforation; in the failure or delay in diagnosis and therapy of the same complicating situations; in the unavailability of emergency units and inadequate organization of a timely connection with a reanimation unit or with a department of surgery; in the failure to provide cardiac monitoring in cases of risk for vagal crisis, as in gallbladder manoeuvres.

• *Hygienic-preventive precautions.* A complicating infection after an echographic operation could be related to a lack of prophylactic procedures in the hospital against infections [3, 4, 5]. Particularly, in the case of treatment of patients with AIDS or those who are HIV seropositive, the administrative staff have total responsibility towards operating personnel, in the adoption of the adequate norms of protection.

• In *delegation* and *vigilance.* The right and duty of the physician to learn the technique and practice in real cases cannot disguise or weaken the obligation of the managerial figure to choose and monitor the operator [6]. Though the liability of the latter is not removed (because the more unskilled he is the more diligent and prudent he must be), the liability of the managerial figure exists in any case ("culpa in eligendo" or "culpa in vigilando" for entrusting subjects not fit or not sufficiently experienced), except in the event that he can prove that the accident has happened beyond his control ("act of God or force majeure").

In a concise but necessarily incomplete way, we will examine the juridical subjects of liability for medical torts, comparing Anglo-American law (common law) with that of countries regulated by an encoded law (civil law), typically derived from Roman law, such as that of Italy.

In *common law* countries, since the last century, *medical malpractice* has been considered as a particular kind of "tort of negligence," regarded as a breach of "duty of care" Though the traditional Anglo-american judicial system is founded on jurisprudence, based upon forms of action, it has gradually moved towards the formulation of a general theory of tort, that has analogies with the codes of norms in Italy and in France [7, 8, 9, 10].

In this way, in medical malpractice, the patient has to prove, as for any other tort recognized by jurisprudence, not only the damage he has suffered, but individualize the wrongful act committed by the physician too, providing the jury with the constitutive elements of tort. The proof, however, is traditionally obtained by means of an expert witness [11, 12].

The weakness of this system is revealed in an attitude of corporative protectionism ("community of silence," "shroud of silence," "conspiracy of silence," "fraternal comradeship") that has been finely stigmatized in a New Jersey Supreme Court sentence [Steirginga *v* Thron (NJ SC 1954) 105, A2d, 10], in the name of the duty of physicians both towards the society and towards professional decorum. It has provoked a crisis in the administration of justice that has favoured the choice of procedures that could avoid the identification of negligence.

For these reasons and to diminish the objective difficulties by the patient in proving negligence, the courts, reacquiring their autonomous right of making decisions (duty to decide), have decided to judge cases of professional liability relying on "standards of care", that is on homogeneous parameters for every kind of activity, which we can duly expect from any physician performing the same activity [13].

It will not be difficult to identify these minimum standards of care in interventional US either, referring to instruments, to the qualification of the operator, to the care that must be assured before and after the operation.

An other method that has been followed has been that of recognizing in production defects of instruments or other medical devices an automatic kind of so-called "objective" liability. Nevertheless the prevailing guidelines have soon considered the physician and the hospital as suppliers of services (rather than producers or sellers of products) so that they can be held responsible only in actions regarding a tort of negligence, including the omission of information for the patient regarding the risks inherent in the use of a particular instrument or medical device (duty to warn) (14).

The most important juridical instrument that has been introduced to avoid the expert witness in medical malpractice cases and which, in substance, is more and more accepted in civil law European Countries too, is represented by the doctrine of "res ipsa loquitur" or, in mitigated form, of "conditional res ipsa loquitur", suggested by many American Courts. It is the existence of the fact and of its circumstances that creates the hypothesis of negligence. The system is based on three conditions: the damage wouldn't have happened without negligence on someone's part; it has to be caused by a medical operator or by an instrument used by the physician; there is not joint liability for wilful deceit or fault by the damaged part [15].

In *civil law*, derived from Roman law, professional liability is judged on the basis of a code of norms, but today finds solutions nearer to those of common law too.

A typical example is that of Italy, where medical liability in the civil code is considered as a *contractual liability* (art. 1218 c.c.), in that the physician and the patient have tacitly agreed upon mutual obligations; there can also be a converging *tortious liability* (art. 2043 c.c.) for unfair damage (that is, for fault deriving from the violation of the general duty of "neminem laedere," according to doctrine and guidelines of jurisprudence) [16, 17, 18, 19, 20].

The physician is generally bound by an obligation of means (duty of care) towards the patient, directed at the healing or the improvement of the condition, not of the result, the latter being inevitably conditioned also by factors that are beyond the capabilities of Medicine. The duty is the due "diligence", related "to the nature of the activity performed" (art. 1176 c.c.) and often defined by the Supreme Court as that of the "disciplined and conscientious professional": who acts, that is, with diligence, prudence and competence based upon a proper and up to date learning [17].

It is important to evaluate the degree of the guilt: the physician is held responsible for *"culpa levis"* only when he has acted against the rules of diligence and prudence typical of an average prepared professional; he is held responsible only for *gross negligence* for inexcusable error (art. 2236 c.c.) in face of insurmountable technical difficulties, but he will not be pardoned for negligence and imprudence in cases which, for the "special difficulty," require the greatest diligence and due caution.

Contractual liability in interventional US, considered in a wider doctor-patient relationship, certainly retains the significance of obligation of means in therapeutic procedures, but it can take on the meaning of outcome obligation in diagnostic procedures, such as collecting cytological or histological material, aspirating liquid from cysts for laboratory examinations, the targeted injection of contrast medium or other manoeuvres that can be considered complete in their own right.

The juridical distinction maintained between contractual and tortious liability has a practical importance for the burden of proof, so as to obtain indemnity for the patient. In fact, while in the first situation (contractual liability) the defendant (the physician) is obliged a priori to indemnify the damage, unless he is able to prove that the failure has

been induced "by causes not imputable to him", for accidental causes or circumstances beyond his control; in the second situation (tortious liability) it is the claimant (the patient) that must prove the medical error, the professional guilt, the damage suffered and the causal relationship between the latter and the former. The advantageous situation for the claimant in an outcome obligation, in contractual liability, is clear; the situation appears more difficult and weak for the claimant in search of evidence when there is only an obligation of means, a condition nearer to that of tortious liability.

The most recent verdicts have thus tried to moderate the burden of proof on the claimant [21] coming to the conclusion that, if on the basis of statistical data and experience there is a well-grounded expectation of a favourable outcome, as the procedure can be "easily performed", then the defendant is held responsible for not having reached the expected outcome or for having worsened the conditions of the patient, unless he can bring evidence to the contrary (the physician should prove that the action has been done in a correct way and the inadequate outcome has been provoked by an unpredictable supervening event or by the existence of a particular condition not identifiable by a common diligence). It is, in substance, a kind of acceptance of the "res ipsa loquitur" doctrine The "easily performed" procedures are those for which "a common professional learning" is sufficient; in these cases the claimant should only provide "the proof of the procedural characteristics and of the derived pejorative outcome" [19, 20].

A large part of interventional US seems to fall within these cases; it would be useful to identify, in co-operation with experts in the subject, those echographic procedures that could be defined, along with indications jurisprudence, as "performed with difficulty," as they require professional learning higher than that of the ordinary operator.

So far we have mentioned the subjective responsibility (guilty) of the physician, but the hypothesis, in the Italian civil code, of an objective responsibility (indirect) or a responsibility of the Health authority of which the operator is an employee or in which he acts by special arrangements must also be considered [18, 20].

In the case of an objective or indirect responsibility, that is the case of physicians working in private structures, according to the art. 2049 c.c., it has been stated that the damages caused by employees or provoked "in the exercise of the duties to which they are assigned", are refundable by their employers or principals. For this it is enough to be employed in a place where the direction and control are in the hands of a responsible person. The malpractice of the subordinate physician is always important, but the patient could have the advantage of claiming damages from the economically stronger structure (which is usually insured); the latter would then act against the physician, who is eventually held responsible for the reimbursement [18].

The same principle cannot be extended when the employer is a public corporate body, such as the Health authority, because in this case there is no indirect responsibility, but direct responsibility because the corporate body has an organic identification with its employees. The physician's conduct, provided that it is within the aims of the institution, is then directly imputable to the public corporate body and the responsibility of this converges with that of the employees that have caused the damage [18, 22].

In fact, when the patient is admitted to Hospital, the common contract is modified: it is the Hospital that undertakes the duty of care and is held responsible for inaccurate fulfilment (art. 1218 c.c.) of the obligation, caused by guilt (culpa levis) of its own personnel, by organizational, structural and hygienic deficiencies of the corporate body;

the physician who is an employee or who has a special arrangement, instead, being extraneous to a true contractual relationship with the patient (he has a contract only with the corporate body), can be held responsible for unfair damage to the patient for tortious liability (but this, for a public employee, only in case of gross negligence).

Indemnity for damages is usually managed through an *insurance* for the civil responsibility of the physician, where the insurance Company pays directly to the claimant the indemnity owed by the physician or by the corporate body or refunds the insured party the money paid to the claimant [23, 24].
For an adequate guarantee it is advisable that the physician should arrange with the insurer or should pay attention to the features of the policy, which should:
• define, above all, the extent of the guarantee to obtain a real coverage of all the specific activities which could potentially provoke damages;
• not contain disadvantageous exclusion clauses from the guarantee;
• arrange coverage for any degree of guilt, and also of gross negligence, if that distinction is relevant;
• define the threshold insurance amount with an adequate margin of confidence (i.e. the maximum sum agreed with the insurer that will be paid to the claimant for each damage), considering that such a sum is not automatically revalued every year; in the policies that last for many years it would be therefore convenient to consult the insurer to reassess the maximum sum during the course of the contract;
• arrange, with a specific clause, the organizational and economic management of the controversy by the insurance Company, in the name of the insured part, that could be summoned to appear before the civil Court; if necessary, the same Company will designate legal and technical experts and will make use of the faculties and actions due to the insured part [2].

In the specific case of interventional US, for the particular characteristics of the risks, there is no reason to fear higher insurance premiums (which, in the USA, are fixed, in decreasing order, according to the following disciplines: Neurosurgery, surgical Obstetrics and Gynaecology, cardiovascular Surgery and Orthopedics, major Surgery, Anaesthesiology, general Surgery, Obstetrics-Gastroenterology- Urology), but on the contrary lower premiums, as fixed for minor Surgery (which, in the USA, precedes, in the above order, the lowest step occupied by Internal Medicine) [15, 25].
In Italy, hospital authorities, according to art. 29 of the D.P.R. n. 130/1969 were required to guarantee the corporate body and the employees by means of adequate insurance policies for civil responsibility. After the institution of the National Health Service and the involvement of hospitals within the U.S.L., art. 28 of the D.P.R. n. 761/ 1979 transformed the obligation of insurance into a simple faculty, together with the right to the compensation of the insurer from the physician, in cases of "wilful deceit and gross negligence". In fact, today, medical liability insurance must be considered as a tool for a wise administration of the two Italian Health organizations.
Both Health authorities and private ones are usually insured, not only for their direct responsibility, but also for that of their own employees or persons with special arrangements, including the physicians.
It is always the case however that the physician should be aware of the policy stipulated by the employer so that he can verify the extent of the guarantee, the maximum sum insured, the existence or the absence of the right to compensation by insurer from the physician in cases of gross negligence on the part of the same. In case of gaps in

the guarantee against risks, the physician, will evaluate the need for stipulating an individual complementary policy [2].
It must be considered moreover, that the policy stipulated by the corporate body covers only the professional risks provoked by the institutional activity of the same corporate body, not those deriving from free authorized activity, with the use of the corporate body's equipment. In this case, in fact, the physician has a personal contractual relationship with the patient and will answer for inaccurate fulfilment only through a personal insurance policy; the corporate body, instead, through the insurance coverage will answer for contractual responsibility of other additional treatment or procedures, conducted after the medical operation [17].

Informed consent

An *interventional US procedure*, even if only slightly invasive, can modify the physical integrity or determine a risk, though only theoretical. Therefore the *consent* of the patient cannot be considered implicit in the doctor-patient relationship but *must be expressed in an explicit way* [26, 27, 28, 29]. The basis of this right to freedom and self-determination on the part of the patient, is, moreover, in the "Paper of the rights of the patient" of the American Hospital Association, in the "European Guide of Medical Ethics," in the Codes of medical deontology of almost all the Countries of the world, in the Constitution itself of the Italian Republic (art. 13 and 32).
To be *valid*, consent must be genuine and freely given directly by an understanding and informed person, relative to a single relevant diagnostic-therapeutic procedure, given immediately prior to the operation, and can be revoked at any moment.
In order to be able to express his/her will the patient must be over 18 years of age and be fully responsible for his own decisions. Norms of the Italian civil code appear to be a good example and of wide significance. For a minor consent is expressed by the person with paternal authority or wardship; according to a prevailing juridical guideline for the minor who might have reached *natural capacity* (beginning at 14 years of age), there should be mutual consent with those who exercise this authority. In the event that a decision is made against health interest of the minor or in the event of contrast between the parents, the physician could apply informally to the juvenile judge; in urgent cases, however, he will decide directly on behalf of the minor, without consent, "under necessity". For the *disabled* (the person who has lost civil capacity through illness) the same norms of behaviour are to be followed, the deciding figure being the guardian. There is no juridical relevance for the consent of parents of an *incapable* person through illness, as a partially disabled person, but they can be adequately informed. If it is a case of an urgent operation the physician will act only in the interest of the patient's health, resorting to the legal measure of "under necessity" behaviour.; if, on the contrary, the operation is not urgent, in case of a temporary incapability (through unconsciousness) it is convenient to delay the operation, waiting for the patient to regain consciousness and the ability to express a valid consent; faced with a permanent incapability, however, the physician will act directly in the interest of the patient's health, taking into account the opportunity (above all in case of parental opposition) of preventively signalling the case to the judicial Authority, in order to obtain mutual guarantee.
The requirement of awareness is derived from the knowledge of the object of the medical activity, the benefits, the risks, the alternatives and prospects, all of which information is the patient's right. The information, to be clearly understood, has to be supplied in a way which is in keeping with

the culture, the ability and way of living of the patient; his understanding must be verified through the ability of the patient to ask questions or give answers which are coherent with his expressed choice. It is neither necessary nor opportune to bring to the notice of the patient each and every possible risk with relative statistics, that would serve more to intimidate than to inform the patient. The patient must always be at the centre of attention, paying consideration to his individuality and vulnerability: this is why the right to know must not be exaggerated. It may in fact be a right that is not desired by the patient; or else, the treatment may concern a pathology which has a serious or inauspicious prognosis, which the physician could decide to communicate in an incomplete way. This would be sufficient to guarantee an immediate result, but it would not be so complete as to provoke in the patient an emotional attitude which is negative for his own state of health and to the aims of the therapy which has been programmed. In these cases, according to opinions and sensitivity belonging more to Latin countries than those of Anglo-Saxon origin, a reasonable limitation or modification of information is justified and does not jeopardize the validity of the consent.

In particular, in view of the risk of haemorrhage in interventional US, the patient should also be informed that there could be an exceptional need for a transfusion (for which the law itself requires an explicit consent). This could create problems, such as that of absolute refusal through religious conviction (Jehovah's Witnesses). It must be remembered that, in the case of haemorrhage resulting from operation, when there is no alternative to transfusion, the opposition of the parents of the minor has no relevance (they cannot decide against the health interest of the minor); for the fully conscious adult, on the contrary, many authors believe that his will has to be respected. In the case of a supervened unconsciousness (shock) the physician should however have the right and duty to intervene; in fact in these circumstances the patient is not in the position at that moment to express his will (refusal of transfusion), that is the confirmation of the real intention of the patient who finds himself in a reality which has been forecast but not yet experienced.

For an ambulatory or day-hospital interventional US the due information to the patient should entail the following: information regarding the post operative period, possible later complications appearing after the operation with symptoms of alarm relative to the complications requiring immediate treatment; prescribed sanitary controls; precautions to be taken once the patient has left the hospital. The patient will demonstrate the exact understanding of these instructions and acceptance of them; the same information will be given also to relatives for a better and testified responsibility.

From what has been said above it is clear that there must be a written record, for future use, of the consent. This consent can be expressed either by a note on the patient's hospital file or by the use of a predetermined form, if possible modifiable by the individual. The form is not intended as an alternative to the doctor-patient interview but should only constitute a valid record of the information given to the patient, having been compiled in his presence.

Proposal of a form for informed consent in interventional ultrasonography

The undersigned _____
(exercising the paternal authority/wardship on behalf of the minor)

_____

declares

that he has been informed in a clear and comprehensible way by Dr./Prof.

_____

☐ of the need of receiving a diagnostic/therapeutic operation of interventional ultrasonography for

_____

☐ of the characteristics of the procedure that has been proposed, on expected benefits, of foreseen consequences and risks that must in any case be considered theoretical and common to every kind of invasive surgery

or

☐ of the risks that can be considered more frequent than normal on the basis of my particular conditions and in particular,

_____

☐ of the possibility of the need for an homologous blood transfusion,
☐ of the doctors' suggestions to be observed at home, which are

_____

I confirm that I have understood in full conscience what has been written above, that I have been allowed to ask questions and to have been given adequate explanations.
For these reasons *I consent* to the proposed procedure.
(Eventual notes: _____
_____)

Patient's signature _____ Doctor's signature _____

Place and Date _____

References

[1] Carbone A: *Aspetti clinici e medico-legali della radiologia interventistica.* Zacchia, 67: 383-391, 1994.

[2] Brondolo W, Giannini G, Mangili F et al: *Vademecum sulla responsabilità professionale del medico.* Piccin, Padova, 1993.

[3] Bennett JV, Brachman PS: *Infezioni ospedaliere.* Piccin, Padova, 1992.

[4] Gioannini P, Dal Conte I: *Il rischio di trasmissione di malattie infettive in ambito nosocomiale.* In: Martini M, Bruni P (Eds), *Responsabilità professionale da patologia nosocomiale.* Atti Convegno Nazionale di Medicina Legale, USSL, Ivrea, 1994.

[5] Grandi M, Gentilomo A, Mecacci C, Paoletti R: *Infezioni ospedaliere: aspetti medicolegali.* In: Martini M, Bruni P (Eds), *Responsabilità professionale da patologia nosocomiale.* Atti Convegno Nazionale di Medicina Legale, USSL, Ivrea, 1994.

[6] Farneti A: *La responsabilità civile del primario.* In: Fineschi V (Ed), *La responsabilità medica in ambito civile. Attualità e prospettive.* Giuffrè, Milano, 1989.

[7] David R: *I grandi sistemi giuridici contemporanei.* CEDAM, Padova, 1980.

[8] Roddey Holder A: *The duty of care.* In: Abrams N, Buckner MD (Eds), *Medical Ethics.* The MIT Press, Cambridge, Massachussetts, 1983.

[9] Dell'Aquila E: *I principi generali della responsabilità civile nel diritto inglese.* Giuffrè, Milano, 1989.

[10] Penneau J: *Medical Responsibility in France.* In: Deutsch E, Schreiber HL. *(Eds), Medical Responsibility in Western Europe,* Springer Verlag, Berlin, 1985.

[11] Danzon PM: *Medical Malpractice: Theory, Evidence and Public policy.* Harvard University Press, Cambridge (Mass), 1985.

[12] Giesen D: *International Medical Malpractice Law, Mohr (Siebeck)-Nijhoff.* Tubingen-Dordreck, 1988.

[13] Khan AN: *Standard of proof in medical negligence.* Medico Legal Journal, 52: 117-122, 1984.

[14] Cave Bondi G, Ciallella C: *Medical negligence: inquadramento storico della responsabilità professionale nel diritto anglo-americano.* Jura Medica, 8: 7-24, 1995.

[15] Fineschi V: *Res ipsa loquitur: un principio in divenire nella definizione della responsabilità medica.* Riv It Med Leg, 11: 419-454, 1989.

[16] Norelli GA: *Sul divenire della responsabilità in ambito sanitario, Note medico-legali.* Riv It Med Leg, 7: 782 - 811, 1985.

[17] Della Sala P: *La responsabilità professionale.* In: Barni M, Santosuosso A (Eds), *Medicina e Diritto.* Giuffrè, Milano, 1995.

[18] Bilancetti M: *La responsabilità penale e civile del medico.* CEDAM, Padova, 1995.

[19] Zana M: *Le basi giuridiche della responsabilità (civile) medica.* In: Fineschi V (Eds), *La responsabilità medica in ambito civile. Attualità e prospettive.* Giuffrè, Milano, 1989.

[20] Zana M: *Responsabilità medica e tutela del paziente.* Giuffrè, Milano, 1993.

[21] Comporti M: In: Fineschi V (Ed), *La responsabilità medica in ambito civile. Attualità e prospettive.* Giuffrè, Milano, 1989.

[22] Lessona C: *Responsabilità del medico dipendente e dell'amministrazione sanitaria.* Giuffrè, Milano, 1984.

[23] Antinozzi M: *Riflessi assicurativi della responsabilità sanitaria.* In: *La responsabilità in materia sanitaria.* Giuffrè, Milano, 1984.

[24] Martelli L, Mastroroberto L: *Implicazioni assicurative della responsabilità professionale del medico nell'ambito del S.S.N.* In: Fineschi V (Ed), *La responsabilità medica in ambito civile. Attualità e prospettive.* Giuffrè, Milano, 1989.

[25] Gonzalez ML: *Medical Professional Liability Claims and Premiums, 1985-1991.* AMA, Chicago, 1993.

[26] Faden RR, Beauchamp TL: *A history and theory of informed consent.* Oxford

University Press, New York, 1986.
[27] IADECOLA G: *Consenso del paziente e trattamento medico chirurgico.* Liviana, Padova, 1989.
[28] NANNINI UG: *Il consenso al trattamento medico.* Giuffrè, Milano, 1989.
[29] Comitato Nazionale per la Bioetica, Informazione e consenso all'atto medico. Società e Istituzioni, Presidenza del Consiglio dei Ministri, Dipartimento per l'informazione e l'editoria, Roma, 1992.

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