Medico-legal cases

Current trends for medico-legal disputes related to functional nasal surgery in Italy

Attuali tendenze medico-legali in Italia relative alla chirurgia funzionale nasale

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SUMMARY

The problem of professional liability in case of adverse outcomes or failures secondary to surgery is very sensitive in many countries of the European Community. In Italy, a recent sentence of the Supreme Court concerning a patient who underwent septoplasty raised considerable doubts in relation to the guidance to be followed in disputes related to an alleged professional liability, further exacerbating the juridical orientation of recent years in this context. This ruling involves any surgery, as well as rhinologic surgery, and calls into question most regulatory and legal principles that have traditionally been adopted by the Italian Civil Law. The sentence states that the plaintiff is only required to document the failure of surgical treatment, but not the breach of the duty of care by the surgeon, thus shifting the burden of proof to the physician-debtor. It also considers that, in assessing the degree of negligence, reference should be made to the qualifications of the surgeon, according to principles that are not covered by current regulations, denying that in general surgery (i.e., not with aesthetic purposes) the surgeon must only to act with diligence and need not guarantee a favourable outcome. This series of statements, complementing one another and evolving more unfavourably towards physicians, facilitate legal disputes for speculative purposes through complainants, with obvious health and socio-economic implications.

KEY WORDS: Medical liability • Nasal surgery • Duty of care

RIASSUNTO

Una recente sentenza della Corte di Cassazione, riguardante una paziente sottoposta ad intervento di settoplastica, ha destato un notevole interesse: essa, infatti, partendo da un problema limitato alla rinologia, ha in pratica finito con il coinvolgere tutta la chirurgia. Il contenzioso preso in considerazione nella sentenza citata fa riferimento al caso di una paziente a cui era stato prospettato, da uno specialista non coinvolto nella vicenda giudiziaria, un intervento di setto-rino-plastica, con finalità estetiche e funzionali; la malata, però, aveva accettato una semplice operazione di settoplastica in quanto nella struttura pubblica, in cui si era ricoverata, non erano previsti gli interventi di chirurgia estetica a spese del Sistema Sanitario Nazionale. La paziente, dopo qualche anno, si era sottoposta presso una struttura privata ad un nuovo intervento, con finalità sia estetiche che funzionali, in quanto, a suo parere, i risultati della prima operazione non erano stati soddisfacenti. Dopo questa seconda operazione la paziente citava in giudizio il chirurgo che aveva eseguito il primo intervento, per i danni da lei subiti a seguito dell'insuccesso dell'operazione. In I ed in II grado i giudici hanno prosciolto il chirurgo affermando sostanzialmente che nell'intervento da lui eseguito, con finalità esclusivamente funzionali, egli aveva operato correttamente. L'interessata era quindi ricorsa in Cassazione; la Corte di legittimità ha espresso una serie di rilievi critici nei riguardi delle sentenze pronunciate dalle Corti di merito, sulla base dei quali il ricorso è stato in parte accolto e il procedimento rinviato ad un'altra sezione della Corte di Appello per una revisione della sentenza. Nella sentenza oggetto del lavoro si mettono in discussione gran parte dei principi normativi e giuridici che erano stati tradizionalmente adottati dalla dottrina giurisprudenziale in Italia. Infatti tale sentenza: contesta che nella chirurgia generale (cioè con finalità non estetiche) l'operatore debba assicurare solo di agire con diligenza (obbligazione di "mezzi"); sostiene che l'attore sia tenuto a documentare solo l'insuccesso del trattamento sanitario ma non la mancanza di diligenza del convenuto, trasferendo l'onere di questa prova al medico-debitore; ritiene che nella valutazione della diligenza si debba fare riferimento alla qualificazione del convenuto secondo un principio non previsto dalle norme vigenti; afferma che la distinzione di interventi chirurgici di facile esecuzione o di problemi tecnici di speciale difficoltà non può valere come criterio di distribuzione dell'onere della prova, bensì solamente ai fini della valutazione del grado di diligenza e del corrispondente grado di colpa. Si tratta di una serie di indirizzi che, integrandosi a vicenda, rendono estremamente agevoli i procedimenti giudiziari di natura speculativa da parte dei pazienti, con ovvie implicazioni sanitarie e socio-economiche.

PAROLE CHIAVE: *Responsabilità professionale • Chirurgia nasale • Obbligazione di mezzi*

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Introduction

The issue of medical liability is very sensitive in many countries of the European community and other Western societies, regardless of the approach – continental civil law or common law - taken by different legal systems [1,2]. The interest in this issue was recently demonstrated by a survey conducted in 2007, whose results were presented at an international workshop [3], and by the proceedings of a conference held in Strasbourg and curated by the Council of Europe's Public and Private Law Unit [4] in June 2008.

In Italy, a recent ruling by the Supreme Court [5] regarding a patient who underwent septoplasty, has raised considerable concerns in relation to the guidance to be followed in disputes related to an alleged professional responsibility. The conclusions of the sentence have led to radical revision of the legal doctrine for some of the most important medical-legal issues (characteristics of medical obligation, burden of proof, limits of professional liability, assessment of professional diligence, etc.), regardless of the specialization of the defending physician. In the following paragraphs, the ruling of the Supreme Court will be discussed, considering that this sentence seems to counter the greater uniformity of legal criteria and their interpretation, as required by the Council of Europe for the Member States.

Case report

The litigation refers to the case of a middle age woman, to whom septo-rhinoplasty, with aesthetic and functional purposes, had been proposed by a specialist that was not involved in the lawsuit. The patient had accepted the intervention because the aesthetic procedures at the expense of the national health system were not provided in the public institution in which she was hospitalized. After a few years, the patient underwent a new intervention at a private clinic, with aesthetic and functional purposes, as in her view the results of the first operation were unsatisfactory.

The judges acquitted the surgeon in the first and second grade, essentially sustaining that he had operated properly, in full compliance with the duty of care.

The complainant, therefore, resorted to the Court of Cassation which expressed some criticisms concerning judgments by the courts of first and second degree; on the basis of those remarks, the appeal was partly upheld and the case subjected to an other section of the Court of Appeals for a review of the sentence.

Discussion

In recent years, Italy has witnessed a rapid change in the legal interpretation of the physician's professional responsibility. This evolution of ideas has been further consolidated by recent pronouncements of the Supreme Court [5-7], one of which is the subject of this report, considering its particular relevance in otolaryngology surgery [5]. In this respect, it must be pointed out that in Italy the lower courts no longer inaugurate new directions that are later accepted by the judges of legitimacy; currently, the Supreme Court imposes the new directions, systematically nullifying the decisions of the Courts of Appeals [8].

Nevertheless, it should also be noted that the legal principles for the obligation of professional care is applied in a substantially similar manner in all legal systems of EU member states [9], regardless of the juridical doctrine adopted: in surgery without aesthetic purposes, and therefore in rhinologic surgery, the contract established between the surgeon and the patient binds the physician with an obligation, commonly defined as obligation of means or duty of care [10-12]. Briefly, it is required that the surgeon performs his duties with the diligence of the nature of the professional activity exercised. Therefore, the failure of the professional should not be inferred from the non-achievement of the useful result, but it should be assessed with reference to a breach of duty of care.

This principle was blindly followed in Italy until about 10 years ago, even for interventions considered easy to perform, or "routine" procedures. In this sense, for example, the Supreme Court made a ruling in 2001 [13], stating that in case of easy to perform operations a transition does not automatically occur from obligations of means to obligations of results.

The real turning point of doctrine was postponed to 2004, year of the ruling of the Court of Cassation n. 9471 [14], according to which a worsening after easy to perform operations is a presumption of guilt by the physician and the first step of the obligation of the professional from obligation of means to obligation of ("almost") result.

Paradoxically, in the first part of its ruling [5], the Court of Cassation suggests a number of considerations to support the illogic of considering surgical activity in the same way as an obligation to ensure results, asserting that the professional's failure to fulfil his obligation may not be presumed, *ipso facto*, from the non-achievement of the useful outcome that was targeted by the patient, but must be as one of the duties regarding professional conduct. Furthermore, it argues that "the failure is due to negligent performance, not based on the due diligence by the professional (and/or hospital)."

The successive deductions by the Court of Cassation contradict these premises. It in fact affirms that "if the professional activity does not obtain the normal result in relation to the concrete circumstances of the case, the physician is required (especially if the intervention is considered a simple procedure) to give proof of the occurrence of an unforeseeable event that was not surmountable with proper care". The exposed thesis is not shareable: in fact, if the professional's failure to fulfil his obligation may not be presumed *ipso facto* from the defective achievement of

the useful outcome that was targeted by the complainant, it must be inferred that when the patient complains about the surgical failure, he cannot merely document the failure itself, since – as the same Court of Cassation states – this undesirable outcome does not prove *ipso facto* the breach of duty of care by the professional. We do not believe in this regard that a wrongful conduct by the professional should be inferred in case of a defective surgical outcome, likely to be achieved with proper care, taking into account the many unpredictable factors that in medicine and surgery can affect the outcome of a specific treatment (reasoning that may be valid for cases of easy solution, where the unknowns are limited and the outcomes are generally favourable).

In case law the view is generally shared that the different levels of professional specialization, but not qualification (i.e. consultant, medical assistant, etc.), must be related to a different assessment of diligence. In other words, specialization or super-specialization is a factor that can affect the required conduct by the professional and a further aspect on which to concretely evaluate the degree of professional misconduct [9 15].

In some legal systems, including that in Italy, the debtor is held free from liability if the same is facing a particularly difficult technical problem. More precisely, the Italian Civil Code states [16] that if "a work involves particularly difficult technical problems, the work provider shall not respond for harm, but only when he acted intentionally or with recklessness".

The sentence in question affirms that "a limitation of medical professional liability in cases of wilful misconduct or gross negligence (ex art. 2236, Italian Civil Code) concerns only those situations with problems of particular difficulty and in any case concerns only the inexperience and not the carelessness and negligence…*"*.

Given that the care required by the professional to settle the obligation must be determined by taking into account his/her activity and therefore his/her possible specialization, the Supreme Court argues that in assessing any wrongful conduct, the qualifications of the professional must also be considered. In the sentence described herein, it was reported that: "…the conduct of the practitioner (a *fortiori* if one of the best in that area) must be examined not less but rather on the contrary more rigorously for the purposes of professional liability…".

The configuration of diligence in relation to the activity of the surgeon (standard of care) responds to a particular provision of the law; the link between diligence and qualification of the professional is an original thesis, which should not be accepted, finding no support in Italian legislation or, to the best of our knowledge, in other legal systems. In fact, the specialist would be forced to resolve difficult surgical problems in relation on his/her level of preparation; the lack of resolution of these problems could constitute for him/her a presumption of guilt for unskillfulness, not *vs*. a medium standard, but depending on his/her particular qualification.

In other words, the sentence aggravates the liability of the surgeon, especially when skilled and highly experienced, discouraging his participation in operations that could lead to failures and, consequently, increasing risk for patients.

One of the main issues in medico-legal disputes relating to the physician's professional liability is the burden of proof [17 18]. In general, in the case of failure of the surgical intervention and/or if the patient is not satisfied with the surgical outcome and intends to appeal to court to obtain compensation, he will have to prove the failure of the surgeon and his professional liability, with reference to the breach of the duty of care. The proof referred to the surgeon-debtor invests substantially the demonstration that no technical rule has been violated by the surgeon and that the failure was due to a cause not attributable to him/her; in other words, the professional must document to have operated with diligence and prove that he had fulfilled the contractual obligation, as opposed to what is alleged by the plaintiff-creditor.

The Court of Cassation has revised the current addresses concerning medical liability, on the basis of a ruling by the United Sections Supreme Court [19]. This particular ruling concerns a dispute related to the soundproofing of a wall, between a customer and a construction company. Based on this ruling, unexpectedly applied to the medical field, the Court of Cassation states that the patient creditor has merely the burden to attach the contract and its defective execution, while he is not required to prove the fault of the physician and/or of the hospital and its severity.

As for "routine" surgical procedures, it is widely accepted that the aggravation of the complainant's pathology and the onset of new diseases due to the operation presume negligence and inadequate execution, while the physician should prove that the procedures were performed properly and that the worse outcome was determined by unexpected and unforeseeable events. Therefore, for interventions of easy execution the plaintiff must prove the routine nature of the operation, while the professional should demonstrate that the failure was not related to his/her own breach of duty of care.

This has confirmed a juridical orientation introduced in Italy for the first time in 2003 by the Supreme Court [20], according to which the doctor is to be waived from the burden of proof if the case entrusted to him is not highly complex. It has therefore consolidated a controversial, and easier for the complainant, rule of proof, which is based precisely on the identification of high or low difficulty of the operation; for "routine" surgery, the plaintiff need only prove that the intervention was followed by a negative outcome (on the basis of the assumption "res ipsa loquitur"; Latin for "the thing speaks for itself").

This clear "favour", affirmed by the Court for the com-

plainant who is acting for compensation for damages suffered as a result of routine surgery, is extended by the examined sentence to all cases of alleged professional negligence. With regard to interventions that entail particular difficulties, the Court of Cassation states that "it is indeed inconsistent and incongruous to require to the professional to provide appropriate proof to overcome the presumption of guilt against him in the case of easy to perform or routine interventions, throwing back to the patient the burden of proving in clear and specific way the defective modalities, when the intervention is of particular or special difficulty …". The Supreme Court draws also the attention to the fact that precisely in cases in which the employed diagnostic, therapeutic and surgical procedures are very complex it "is undoubtedly the practitioner to know the rules of art and the specific situation… so as to be able to prove compliance with these rules and to justify his choices". The sentence, virtually eliminating the burden of proof for the plaintiff-creditor, exacerbates the position of the doctor-defendant and binds the proof in favour of this latter to specific requirements.

It should be carefully considered that the orientations of the Supreme Court that we have examined are constantly evoked by subsequent judgments regarding other medical-legal litigations which further strengthen the idea that the plaintiff had an easy path for the purposes of compensation [21 22].

In summary, in our opinion, the plaintiff should document the non-compliance to the obligation by the professional and, consequently, the breach of the duty of care by the debtor-surgeon. Professional liability cannot, in fact, be simply presumed on the basis of a result that the plaintiff claims not to have been reached, taking into account the difficulty of excluding speculative interests of the creditor. It is truly perplexing that in a sentence in which the various aspects of the medical liability were so carefully evaluated, the arguments of the Court of Appeals can be considered eccentric and illogical, without taking into account that the respiratory disorders attributed to professional fault were alleged by the plaintiff about two years after surgery.

Conclusions

The reported law addresses, more and more conducive to plaintiff-creditor, have inevitable consequences on the litigations relative to professional liability in the health sector. In many Western countries, as well as in Italy, an over-simplification of the procedural position of the patient tends to increase the risk of claims for speculative purposes with obvious economic implications. The increase in prosecutions and, at the same time, the greater chances of success of the patient who claimed to have suffered damage as a result of surgery or medical treatment has already produced an substantial growth in the price of professional insurance, estimated in Italy to have increased by over 600% during the past decade. From another point of view, the impact that this phenomenon has on the media should be emphasized, because doctors are subjected to censorship by the press and public opinion, even before the trial.

In the sentence examined, the Italian Court of Cassation exasperated some juridical orientations introduced in Italy a few years ago and further consolidated by similar and even more recent judgments. In fact, it states that the plaintiff is only required to document the failure of medical treatment, but not to prove the breach of the duty of care of the professional, shifting the burden of proof on the physician-defendant and considering that in assessing the degree of diligence (and, therefore, the possible breach of duty), the main reference should be made to professional qualifications, according to a principle not covered by current regulations. Moreover, according to this ruling, the distinction between routine surgery and surgery with technical problems of special difficulty cannot be used as a criterion to distribute the burden of proof, but only for the purpose of assessing the degree of diligence and the corresponding degree of fault of the doctor-debtor. Finally, the principle according to which in general surgery (i.e., not with aesthetic purposes) the physician has exclusively an obligation of "means" is subject to contestation by the Court, despite an almost constant orientation in jurisprudence. In conclusion, we point out that the principles set forth in the ruling of Italian Court of Cassation, complement one another and facilitate lawsuits by patients, even with speculative intent, with obvious socio-economic and health implications.

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