

Some Ethical Legal Issues in Heart Disease Surgery

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Ethical concerns, cultural norms, and legal issues must be carefully considered when treating a patient with heart disease. Although physicians or surgeons must play a role in course of treatment decision making, they should be guided by evidence-based data and the preferences of patients and/or the patient's parents. However, there is no obligation to provide this type of informed consultation and approval unless these ethical issues become law – which typically occurs through litigation. In this review, we examined common ethical principles that are integral to the regular decisions made by clinicians every day. Some special ethical issues and associated litigation, if any, which might occur perioperatively will also be reviewed. Finally, the final judgments of civil and criminal courts of Taiwan, particularly lawsuits involving physicians associated with coronary artery disease care or aortic aneurysm, will also be introduced.

Key Words: Criminal lawsuit • Medical ethic • Medical litigation • Medical negligence

BABY DOE LAW¹

The central challenge relating to medical ethics is that there is no standard way of performing many coronary-related surgeries, where sometimes even routine procedures can involve controversy. Opinions about a child's "quality of life" might be the main issues in the medical care of a child after an accident or medical injury has occurred. In 1984, the United States passed the "Baby Doe" Law or Baby Doe Amendment, an amendment to the existing Child Abuse Law that set forth certain specific criteria and guidelines for the treatment of seriously ill and/or disabled newborns. The law has been controversial in that it dictates what must be done for a child, regardless of the wishes of the parents. The Baby Doe Law mandates that states receiving federal

money for child abuse programs develop procedures to report medical neglect, which the law defines as the withholding of treatment unless a baby is irreversibly comatose or the treatment is "virtually futile" in terms of the newborn's survival. However, opinions about a child's "quality of life" should not be valid reasons for withholding medical care.

The law came about as a result of several widely publicized cases involving the deaths of handicapped newborns. They died when necessary medical treatment was withheld, where they starved and lacked any hydration. The primary case was a 1982 incident involving "Baby Doe", a Bloomington, Indiana baby with Down syndrome whose parents declined surgery to fix esophageal atresia with tracheoesophageal fistula, leading to the baby's death. C. Everett Koop was the U.S. Surgeon General at the time of this incident, who argued the child was denied treatment (and food and water) not because the treatment was risky but rather because the child was mentally retarded. Koop commented publicly that he disagreed with such withholding of treatment. In his decades as a pediatric surgeon, Dr. Koop had repaired hundreds of such defects, with a continually improving rate of success. By 1982, success was nearly certain if the necessary esophageal surgery was performed. A similar situation occurred in

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1983 involving a “Baby Jane Doe” which again brought the issue of withholding treatment for newborns with disabilities within the public eye. In this case, Baby Jane Doe was born with spina bifida, an abnormally small head, and hydrocephaly. Dr. Koop advocated medical treatment despite the severity of the condition and the limited range of outcomes that could result.

Koop’s efforts to educate Congress about this issue ultimately led to the Baby Doe Amendment (U.S.C.A. title 42, chapter 67, sec. 5106a). On October 9, 1984, the amendment extended the laws defining child abuse to include the withholding of fluids, food, and medically indicated treatment from disabled children. The law went into effect on June 1, 1985.

In Taiwan, there is no similar law to protect disabled children, not in “The Protection of Children and Youths Welfare and Rights Act”, the “Medical Care Act”, or the “Hospice Palliative Care Act”. However, the protections and concerns underscored by the US law can be a part of ethical discussions in the surgery of patients with congenital heart disease (CHD).

PRINCIPLE OF PATIENT AUTONOMY AND SURROGATE DECISION MAKERS

The basic concept of patient autonomy is generally well-respected both ethically and legally. It assumes that a patient should be able to understand the character and nature of an intervention, and consent to or refuse it. Adult patients are presumed to have decision making capabilities unless they are incapacitated or declared incompetent by a court of law.² In Taiwan, the “Medical Care Act”, paragraph 1 of article 63, which mandates that: “Medical care institutions shall explain the reasons for surgical operation, success rate, possible side-effects and risks to the patient or his/her legal agent, spouse, kin, or interested party, and must obtain his/her consent and signature on letter of consent for surgery and anesthesia before commencing with surgical procedure” clearly demonstrate this policy.

Most patients with CHD, typically children (less than 12 years old) or youth (12 to 18 years old), defined by article 2 of “The Protection of Children and Youths Welfare and Rights Act”, do not have the capacity to make medical decisions. A close relative or their parents can be-

come a surrogate decision maker for the minor (2nd paragraph of article 63 of “Medical Care Act”. The legal agent, spouse, kin, or interested party may sign the letter of consent referred to in the preceding paragraph in case the patient is a minor or unable to affix the signature personally.). Children should be involved in decision making at a level appropriate for their maturity and should be asked to consent to healthcare decisions when able. Although persons less than 18 years of age rarely possess the legal authority to consent to their own health care except under specific legally defined situations (i.e., emancipated minors and for specific health conditions such as sexually transmitted diseases and pregnancy), the dissent of an older child should be taken seriously. If parents and an older child are in conflict about a treatment plan, every effort should be made to resolve the conflict. The use of force is rarely appropriate in the delivery of medical care to adolescents.² In Taiwan, the “Medical Care Act” does not have similar litigation and associated caselaw. However, the 2nd paragraph of article 1089 of the “Civil Code” which showed “If there is inconsistency between the parents in the exercise of the rights in regard to the grave events of the minor child, they may apply to the court for the decision in accordance with the best interests of the child”, might apply to this situation. The ethical and legal issues associated with blood transfusion to the minor patient of Jehovah’s Witnesses are good examples of this situation.

Regardless of underlying medical considerations, Jehovah’s Witnesses advocate that physicians should uphold the right of patients to choose what treatments they do or do not accept (though a Witness is subject to religious sanctions if they exercise their right to choose a blood transfusion).³ Accordingly, US courts tend not to hold physicians responsible for adverse health effects arising from the patient’s own requests. However, the point of view that physicians must, in all circumstances, abide by the religious wishes of the patients is not acknowledged by all jurisdictions, such as was determined in a case involving Jehovah’s Witnesses in France. In Taiwan, most surgeons will attempt to use alternatives to avoid blood transfusion. Nonetheless, medical personnel were found guilty under criminal law and sentenced after lethal complications following bleeding from a traffic accident caused by hyperbaric oxygenation in a patient with severe heart failure and dyspnea due to severe anemia.

This adult patient refused blood transfusion, which would have been the safest and easiest way to treat his anemic conditions. In another matter, the High Court verdict determined that physicians should be responsible for undertaking a risky procedure, even if the patient refused a considerably safer treatment (criminal judgment of Taiwan High Court medical appeal No. 2, 2010). In Taiwan, it is quite paradoxical that it is lawful to let a Jehovah's Witness patient die without a blood transfusion. However, the physicians may be found guilty if he tries to save the patient using a substantially riskier alternative.

The situation has been subject to some controversy, particularly when children are involved. In the United States, many physicians will agree to explore and exhaust all non-blood alternatives in the treatment of children at the request of their legal guardians. Some state laws require physicians to administer blood-based treatment to minors if it is their professional opinion that it is necessary to prevent immediate death or severe permanent damage. Kerry Louderback-Wood has claimed that Jehovah's Witnesses' legal corporations are potentially liable for significant claims for compensation if the religion misrepresents the medical risks of blood transfusions. Wood claims that constitutional guarantees of freedom of religion do not remove the legal responsibility that every person or organization has regarding misrepresenting secular fact.⁴ In Japan, a physician was found not guilty after providing a blood transfusion to a traumatized minor child against the wishes of his parent (Japan Kawasaki Simple Court Judgment 1988/8/20).

PRINCIPLE OF BENEFICENCE AND INNOVATION IN SURGERY FOR CONGENITAL CARDIAC DISEASES

Beneficence means promoting what is best for the patient. The general moral principle of doing good to others is focused by the larger lens of a doctor being in a professional caring relationship with the patient. The definition of "what is best" may derive from the health professional's judgment or the patient's wishes; the decisions of patients and doctors are generally in alignment, but may diverge in some instances. Beneficence implies consideration of the patient's pain, their physical and mental suffering, the risk of disability and death, and their quality of life. At times, beneficence can sim-

ply mean a lack of intervention if the benefit of proposed therapy would be minimal.⁵

In medicine, innovation generally involves the introduction of a new method, idea, treatment, medication, or device to benefit the individual patient. Innovation in cardiovascular surgery has resulted in the development of the heart-lung machine, open heart surgery, the intensive care unit, and strategies of myocardial protection, as well as countless new operations, modified procedures, and new devices. It has been said that nothing is new under the sun. However, it was clear that the introduction of operations such as transplantation of the heart, the Ross Procedure, the Fontan procedure, the arterial switch operation, the Norwood operation and the Maze procedure were all new and relatively untested at one time or another. Clearly, the best way to introduce innovation into clinical practice is by "evidence-based decision making". As Douglas Altman states, "Well-designed and properly executed randomized, controlled trials provide the best evidence on the efficacy of health care interventions". However, randomized controlled trials in surgery are difficult to perform. Observational studies can establish associations rather than causation between treatment and outcome. They can be a valuable alternative when ethical considerations, costs, resources, or time prohibit one from designing a randomized controlled trial.⁶ In Taiwan, innovation in surgery should be regulated not only by the Internal Review Board of the medical institutes, but also controlled by the government, through the Ministry of Health and Welfare (Human Body Research Act).

PRINCIPLE OF NON-MALEFICENCE, LIVE CASE DEMONSTRATIONS OF INTERVENTIONAL CARDIOLOGY PROCEDURES, AND HOSPICE CARE

Non-maleficence means do no harm. In most cases where sick patients are treated, this adds little to the beneficence principle. But most treatments involve some degree of risk or potential side effects, so this principle reminds us to ponder the possibility of whether or not our actions actually do harm, especially if a cure is not possible. In dealing with healthy people (e.g., preventive care, immunizations), do the benefits outweigh the potential harms? Remember that medicine

does have an extensive history of doing harm. In the 18th and early 19th centuries, surgery was extremely dangerous and highly lethal, where giving birth in hospital led to higher maternal mortality than home births. Yet such problems are not entirely a matter of the past. The recent outbreaks of *C. difficile* infection in Quebec hospitals which killed 100 patients by early 2004 suggest that these types of problems continue.⁵

Professional meetings using live case demonstrations to present cutting edge technology are considered a valuable educational resource. Yet there is an ongoing discussion on whether patients who are treated during these live case demonstrations are exposed to a higher risk. Between 1998 and 2010, 101 patients were treated during live transmissions from a single center during 15 invasive-cardiology conferences. In this consecutive series of live demonstration interventional cardiology procedures, the procedural and 30-day clinical outcomes were similar to those found in daily practice and to those that have been reported in the contemporary published data. These results suggest that broadcasting case demonstrations in selected patients from certain centers may be safe.⁷

Hospice palliative care is a good example of non-maleficence. In Taiwan, end-stage heart failure is one of the indications of hospice palliative care if a heart transplant is contraindicated. According to the "Hospice Palliative Care Act" article 3, patients with CHD should be terminally ill, incurable, with supporting medical evidence indicating a fatal prognosis in the near future. The terminally ill patients can choose not to receive cardiopulmonary resuscitation, and reject or terminate life-sustaining treatment. In order to ensure that the patient's wishes are carried out, a signed letter of intent is required. If the letter of intent is signed by and for a minor, the consent of his/her legal representative shall also be obtained. When a minor is unable to express his/her will, the legal representative shall sign the letter of intent (Article 7, paragraph 2, subparagraph 2).

PRINCIPLE OF JUSTICE, FUTILITY, EXTRACORPOREAL LIFE SUPPORT, VENTRICULAR ASSIST DEVICE, AND HEART TRANSPLANTATION

All patient populations have to exist within the real-

ity that medical resources are limited. Physicians cannot cure everybody and so priorities of care must be set (hence the notion of triage). When medical care is allocated, the Justice principle holds that patients in similar situations should have access to the same care, and that in allocating resources to one group we should assess the impact of this choice on others. In effect, is the patient's request fair? Will it lead to a burden to others, such as family caregivers, or other patients at a neighborhood clinic with few resources? While a doctor's primary duty is to the patient, others will be affected by these decisions leading to a "tension" between beneficence, autonomy and justice for the patient.⁵

If the targeted goal of a medical treatment cannot be achieved, the treatment is considered futile. The key determinants of medical futility are length and quality of life. If an intervention cannot establish any increase in the length or quality of a patient's life, that intervention is futile. Nonetheless, patients or their families may ask physicians to provide care that is inappropriate. Physicians, however, are not obliged to provide such care when there is scientific and social consensus that the treatment will be ineffective.²

Significant advances have been made in extracorporeal life support (ECLS), which has resulted in the increased use of post-cardiotomy extracorporeal membrane oxygenation. Retrospective studies have contributed to the ongoing evolution of selection criteria for post-cardiotomy extracorporeal membrane oxygenation. Current indications include failure to wean from cardiopulmonary bypass, haemodynamic collapse, pulmonary hypertension, post-repair of hypoplastic left heart syndrome, or the need for a bridge to transplantation. Although short- and mid-term results are improving, ethical concerns still attend the process. Moral risks related to post-cardiotomy extracorporeal membrane oxygenation may be encountered before, during, and after the open heart procedure. At each stage of the decision making process, moral risks are encountered in many factors that may result in decisions potentially contrary to the best interests of the patient, parents, or use of shared societal resources. These moral risks center around the selection process, informed consent, decision making in the operating room, and post-operative maintenance of extracorporeal membrane oxygenation. Consideration of such risks is affected by questions of

haemodynamic stability, haematologic compromise, neurologic status, and family concerns. We conclude that a thorough understanding of the relevant scientific literature, heightened awareness of moral risks, and incorporation of ethical tenets in clinical deliberation will guide the clinician to make the right decision.⁸

There are many potential and realized ethical issues that arise with the application of mechanical circulatory support to all patients with CHD and adults with CHD in particular, including the necessity of prospective and randomized trials, proper oversight of new therapies, distributive justice regarding equitable access to this potentially life sustaining therapy, and transparency in reporting. Additionally, there are ethical considerations relevant at a macroeconomic level as long-term ventricular assist device (VAD) support is highly resource-intensive in a resource-limited society. As VADs are used with increasing frequency to successfully bridge patients to transplant, there are increased demands on an already insufficient donor pool. These issues, and possible new ones yet envisioned, are likely to become even more prominent as more patients with CHD are supported with VADs.⁹

Heart transplantation in children has evolved from a simple experimental procedure to a revolutionary therapy, unanimously accepted as the only therapeutic method capable of ensuring survival for a large number of children diagnosed with final stage cardiomyopathy, left heart hypoplastic syndrome, obstructive rhabdomyoma, and multiple fibroma. The most serious aspect in pediatric heart transplantation which causes ongoing ethical challenges is the small number of donors available to serve an unquenchable organ demand. Small children under 2 years of age rarely die in circumstances that would offer them the possibility of becoming donors. Under these conditions, a large variety of ethical dilemmas come into focus: is the anencephalic newborn or infant a viable source of organs? How will the distribution of available organs take place? Can a patient who has already benefited from transplant undergo other transplants while other patients die waiting for a new heart? Who makes the decisions in the case of children and teenagers with dilated cardiomyopathy (DCM) and how objective are these decisions? What is the role of pediatric bioethical commissions in making decisions about children with DCM? Which team is capable of

identifying and solving the ethical problems which come into perspective concerning this disease, a devastating diagnosis which has a high risk of premature death in the absence of transplant?¹⁰

In Taiwan, the contraindications of ECLS, VAD, and heart transplantation in patients with CHD are:

1. Irreversible brain damage.
2. Terminal stage of malignant tumor.
3. Irreversible severe illness.
4. Progressive degenerative systemic illness.

The medical profession has long subscribed to a body of ethical statements developed primarily for the benefit of the patient. As a member of this profession, a physician must recognize responsibility to patients first and foremost, as well as to society, to other health professionals, and to self. The following Principles adopted by the American Medical Association¹¹ are not laws, but standards of conduct which define the essentials of honorable behavior for the physician.

- I. A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights.
- II. A physician shall uphold the standards of professionalism, be honest in all professional interactions, and strive to report physicians deficient in character or competence, or engaging in fraud or deception, to appropriate entities.
- III. A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient.
- IV. A physician shall respect the rights of patients, colleagues, and other health professionals, and shall safeguard patient confidences and privacy within the constraints of the law.
- V. A physician shall continue to study, apply, and advance scientific knowledge, maintain a commitment to medical education, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated.
- VI. A physician shall, in the provision of appropriate patient care, except in emergencies, be free to choose whom to serve, with whom to associate, and the environment in which to provide medical care.
- VII. A physician shall recognize a responsibility to par-

ticipate in activities contributing to the improvement of the community and the betterment of public health.

- VIII. A physician shall, while caring for a patient, regard responsibility to the patient as paramount.
- IX. A physician shall support access to medical care for all people.

MEDICAL MALPRACTICE JUDGMENTS FROM DISTRICT CRIMINAL COURTS IN TAIWAN¹²

All medical malpractice judgments from the district criminal courts within Taiwan's 21 district courts during the period of January 1st, 2000 to June 30th, 2008 were included in this study. A total of 223 eligible cases and 312 physician-defendants were included. Of all 223 cases, 128 cases (57.4%) were prosecuted by district attorneys, and 95 cases were pursued by private parties. During the court process, medical expert opinions were sought in 204 cases (91.5%). On average, a malpractice lawsuit took 3.12 years to complete, from the time when medical injury occurred to the time court decision was made. Of the 312 defendants in our study, 110 defendants (35.3%) worked in medical centers, 70 defendants (22.4%) in regional hospitals, 58 defendants (18.6%) in local hospitals, and 55 defendants (17.6%) in clinics. Of the total defendants, 82 (26.3%) were surgeons, 64 defendants (20.5%) were internists, 50 defendants (16%) were obstetricians/gynecologists, 40 defendants (12.8%) were emergency specialists, 23 defendants (7.4%) served as orthopedic surgeons, and 10 defendants served as pediatricians. In terms of court decisions, 232 defendants (74.4%) were found not guilty, and 80 defendants (25.6%) were found guilty. Of those defendants found guilty, 64 (80%) were given probation or amerce. Only 16 defendants (20%) were at risk of confinement. Among the 312 physician defendants who were judged by a professional court, whose professional conduct was considered acts of malpractice by medical experts, who were judged by only one judge and who were prosecuted by district attorneys, they were more likely to be found guilty. Patients who were injured from medical malpractice accidents were more likely to use the private prosecution procedure, and to sue more than one defendant.

In general, medical malpractice lawsuits had a low conviction rate, the punishment tended to be trivial, and the process lasted a long period of time. Based on the findings, decriminalization of medical malpractice may seem to be an option.

OVERRULED CRIMINAL JUDGMENTS TO MEDICAL MALPRACTICE IN TAIWAN¹³

Taiwan is the only country in the world that punishes physicians with medical malpractice by routinely using the criminal legal system, while most countries settle almost all medical disputes with civil action. In Taiwan, criminal suits account for 79% of all medical malpractice law suits.

There were 15 judgments that were overruled, (and thus final and not appealable), and these judgments of criminal prosecutions were collected from February 1, 2002 to January 31, 2005. It was found that in these 15 criminal prosecutions, 16 doctors out of a total 18 defendants lost their trials, which indicates, statistically, that one doctor was found guilty and sentenced per every 3 month period of time. Out of these unlucky medical practitioners, two-thirds of the criminals were surgeons, one-fifth internists, and the rests are gynecologists and pediatricians. The average of the terms of imprisonment was 6.6 months and, fortunately, all of them obtained probation or replacement with forfeit. In these cases, most of the doctors came from local hospitals or clinics, while only two were from the medical centers. Concerning the disputes themselves, five cases involved delayed or missed diagnoses and the other ten involved surgical complications.

In the first 4 years of the 21st century, there was one physician in Taiwan sentenced guilty per every 3 months, which is a unique phenomenon around the globe. The criminal rate of physicians in Taiwan is the highest in all professionals in the world. Most of these doctors were the laborious, life-saving surgeons, internists, pediatricians, and gynecologists. According to the causes of these disputes, the differences between the expectations of the doctors and those of the patients should be addressed by the informed consent doctrine to avoid excessively expensive defensive medicine.

Table 1. Overruled judgments¹³

	Surgeons 10	Internists 3	Others 2
Defendants	Orthopedic 3, Neuro 2	General 2	Gynecologist 1
Physicians	Plastic 2 Pediatric 1 Urology 1 General 1	Nephrologist 1	Pediatric 1
Causes of disputes	Postop complications Bleeding 5 Fatembolization 2 Stroke 1 Intestinal perforation 1 Compartment syndrome 1	Misdiagnosis AMI 2 Cardiac tamponade 1	Misdiagnosis Myocarditis 1 Cervical cancer 1

MEDICAL MALPRACTICE JUDGMENTS FROM DISTRICT CIVIL COURTS IN TAIWAN¹⁴

All judgments arising from medical malpractice suits at the 28 district civil courts in Taiwan from 2000 to June 30, 2008 were designated as appropriate for our study, and a total of 372 cases and 560 defendants were thereafter identified. Out of the 372 cases, the plaintiffs were successful in only 69 (18.5%). The average monetary compensation awarded to plaintiffs was 3,723,171.58 NTD, but it ranged widely from a maximum amount of 27,462,579 NTD to a minimum of 56,325 NTD. Most monetary compensation was between 1 million and 5 million NTD. Compensation was the highest for severely injured, followed by death (15,021,175 NTD), and the lowest (2,958,689 NTD) for other injuries/damages. Among 560 defendants, 29 (5.2%) of them were medical care institutions, and 531 (94.8%) of them were health professionals. Of these healthcare professional defendants, 469 (88.3%) were doctors. The top three specialties were surgery (92 people), obstetrics/gynecology and pediatrics (90 people), and internal medicine (89 people). The average time from the event of medical malpractice to district court decision was 4.2 years. Overall, it ranged from a maximum of 20 years to a minimum of one year. Preliminary results indicate that accessing professional medical courts and ordinary courts, filing criminal suits, having a lawyer, and hospital level were significantly associated with court rulings. Of the 122 cases where both criminal and civil suits were filed, the criminal court rulings were unknown in 37 cases. For the remaining 85 cases with known judgments, the civil

and criminal court rulings were consistent in 65 cases, and were inconsistent in 20 cases. More specifically, the plaintiffs won the criminal suits but lost the associated civil suits in 5 cases; correspondingly, the plaintiffs lost their criminal suits but won civil suits in 15 cases.

LAWSUITS AGAINST PHYSICIANS DEALING WITH AORTIC ANEURYSM¹⁵

Aortic aneurysm, including aortic dissecting aneurysm, is a challenging disease concerning both its diagnosis or treatment. From 1996 to 2009, 25 physicians dealing with 16 patients with aortic aneurysm were sued for medical negligence through criminal prosecution (11 cases) and/or civil remedy (6 cases). One obstetrician was sued both criminally and civilly. The judgments of these cases are analyzed by using "the content analytic method". All patients died of ruptured aortic aneurysm or aortic dissection, or their complications. In 7 patients, alternative diagnoses were made acute myocardial infarction (AMI) 2, gastrointestinal lesions 5. In 3 patients, delayed diagnosis was made until hemodynamic changes occurred. In 3 patients, rupture of the aortic aneurysm occurred after treatment of the patient's primary diseases. In most patients, atypical presentations of the aneurysm were noted. Two surgeons were sued for postoperative complications and one surgeon was sued for delayed operation. Concerning the subspecialties of the physicians, 9 were emergency medicine doctors, 8 were medical physicians, 2 were obstetrics and gynecology doctors, 2 were cardiologists,

and 4 were cardiovascular surgeons. One gastroenterologist who was sued for treating type A aortic dissection as acute cholecystitis, lost the criminal trial and was sentenced to 6 months imprisonment with 2 years forfeit. The judges asked that the physician strive to make a correct diagnosis following a thorough examination and testing, to prevent an incorrect diagnosis and treatment delay of the underlying disease. Aortic aneurysms are difficult to diagnose, especially with atypical presentation. It should always be listed in the differential diagnosis. The judges requested that complete studies be routinely undertaken to enhance the likelihood of a correct diagnosis, which will increase the cost of defensive medicine.

LAWSUITS AGAINST CARDIAC SURGEONS AND INTERVENTIONISTS DEALING WITH CORONARY REVASCULARIZATION IN TAIWAN¹⁶

Coronary revascularizations are high risk operations. Disputes will occur between physicians and patients (or their family) if results do not meet their expectations.

In Taiwan, there are 90 cardiac surgeons and 210 cardiac interventionists who deal with coronary revascularization on a daily basis. A full 10 out of the 12 accused physicians came from tertiary referred centers. There was no difference in the risk of being sued between cardiac surgeons and interventionists, ($p = 0.2219$). In fact, all patients died. These patients were treated as follows: coronary artery bypass graft (CABG) 6, primary PCI in AMI patients 3, elective percutaneous coronary intervention (PCI) 2, thrombolytic therapy 1. It was found that surgeons were sued for postoperative bleeding in 4 cases and stroke in 2 cases. Interventionists were sued due to procedural complications: sudden death in 3 cases, coronary arteries dissection in 1, bleeding with cardiac tamponade in 1, and cerebral hemorrhage in 1. Two trials were lost, and both were elective procedures (CABG and PCI). Interestingly, physicians won all the trials involving emergency procedures, which indicates that judges encourage physicians to save life through high risk emergency procedures. One surgeon, sued for repeated postoperative bleeding after CABG, was sentenced to 6 months of imprisonment with 2 years forfeit. The judges asked the surgeon to react promptly to postoperative bleeding. Another interven-

tionist and hospital lost the civil trial, where they had been sued for collapse after elective PCI due to coronary artery dissection. Judges said that alternative methods, especially CABG, should be described to patients before performing PCI. Besides, a surgeon with an operation room should be available while performing PCI.

The surgeons and interventionists treating coronary artery disease patients with revascularization should follow the standard of care, especially when facing complications. The general rule is: the earlier that actions can be taken to treat postprocedural bleeding, the better. Complete disclosure of life-threatening complications (sudden death or stroke) and alternative methods of treatment (CABG) should be carried out before coronary revascularization. Ultimately, the extent to which the hospital and its doctors will be responsible is the decision of the judges.

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