



# Study on Litigation-expertise of Sudden Pulmonary Embolism for Laparoscopic Inguinal Hernia — Case Report and Literature Review

Jie Zhang, Zihui Cheng, Lingjie Kong, Liang Wang, Ze Liu, Long Yu, Songyue He

Beijing Fayuan Forensic Science Evidence Expertise Centre, Beijing, China

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**Abstract:** With the development of new concepts and technologies of laparoscopic diagnosis and treatment, inguinal hernia repair is increasingly and widely used in clinical practice, and accordingly, the corresponding complications of deep vein thrombosis have also attracted clinical attention. Deep-venous thrombosis and pulmonary embolism have become one of the potential and very dangerous serious complications in patients with inguinal hernia. One case of sudden pulmonary embolism shortly after the laparoscopic inguinal hernia repair was reported in this paper, the patient has been trapped in a persistent plant survival state after rescue. The patient was a male, 67-year-old patient with up to 4 hours of operation, and no available clinical evidences about operative vascular injury have been found, however, this case have been triggered a civil lawsuit for medical damages and the filing of a judicial expertise. Combined with the disputes of this case and the results of the technical review, the legal related preoperative notification and informed consent, the requirements and functions of working system before operation, the preoperative examination and the related surgical risk-factors of pulmonary embolism are discussed. It is suggests that the preoperative discussion, preoperative examination and preoperative notification of laparoscopic inguinal hernia should be paid great attention to in clinical work, and form an institutionalized and normative workflow, which plays an important role in effectively controlling the operation time, reducing surgical complications and avoiding medical disputes.

**Keywords:** laparoscope, inguinal hernia, pulmonary embolism, medical litigation, judicial expertise

## 1. Introduction

Inguinal hernia, including inguinal oblique hernia,, direct inguinal hernia, femoral hernia, etc., is regarded as a common and frequently occurring disease in general surgery, of which indirect inguinal hernia is most commonly discovered, especially in the elderly. In the treatment of inguinal hernia, surgery serves as the best way to treat inguinal hernia. In the previous clinical literature, some cases of pulmonary embolism have been reported[1][2][3][4] in traditional inguinal hernia surgery of inguinal hernia, but it has not caused the necessary clinical research and attention. With the continuous development of laparoscopic technology in inguinal hernia surgery, deep-venous thrombosis (DVT) and complications related to laparoscopic inguinal hernia surgery have gained increasing attraction in clinics[5][6]. However, the cases of acute pulmonary embolism after laparoscopic inguinal hernia surgery are very rare in the existing clinical literature. This paper reports a case of pulmonary embolism after laparoscopic inguinal hernia repair at the end of the anesthesia recovery period and caused a civil lawsuit, so as to strengthen the prevention of doctor-patient disputes and improve the clinical diagnosis and treatment technology and standardization.

## 2. Case report

The patient is a male aged 67. On some day in October 2020, he was hospitalized for a month after a reversible mass in the right lower abdomen was discovered. Specialist examination showed soft abdomen, no tenderness and rebound pain. The right lower abdomen groin area can be palpable with a mass of about 5\*4\*3cm in size, with good mobility, which can be incorporated into the abdomen by manipulation. After the finger pressure internal ring mouth, the swelling mass does not return. Preoperative auxiliary examination of lung function, electrocardiogram, blood routine examination, liver and kidney function and coagulation function showed no abnormality. The patient denied any diagnosis with hypertension, diabetes, coronary heart disease and lung diseases. No obvious abnormality was found in cardiopulmonary auscultation, and the disease was clinically diagnosed with right oblique inguinal hernia. Preoperative record showed that an communication with patients had been conducted, and minimally invasive surgery treatment was initially proposed by patients. After preoperative discussion, TAPP under general anesthesia was proposed, and Informed Consent for Surgery was signed with the patient

before surgery, and no abnormality was found in visit in preoperative anesthesia. Caprini thrombosis risk assessment scale was used before signing anesthesia informed consent, and the score was 4, which was determined as medium risk.

CO<sub>2</sub> pneumoperitoneum was established on the umbilicus cord after general anesthesia on the operation day, and the intra-abdominal pressure was set at 12mmHg. The body position of head-down and left-side horizontal position was set about 15 degrees each. 1.1-cm trocar was placed the umbilicus edge and paraumbilical right axillary front, and the umbilical level of 2cm below the external edge of the left rectus abdominis was disposed at 0.5cm Trocar, Laparoscopy and corresponding operating instruments were placed respectively. Intraoperative exploration showed that the small intestine adhered to the inner ring mouth, which was serious adhesion and difficult separation. During the operation, blunt union was used to separate the adhesion. An curved incision was made along the right anterior superior iliac spine and the 2cm of the inner bladder and the upper edge of the inner ring mouth. The peritoneum was cut and the anterior bladder space was separated from the opposite side of the pubic symphysis by blunt union more than 2cm from the medial side. The incision was dissociated from the upper peritoneum to the anterior superior iliac spine. The hernia sac and spermatic cord were separated along the lower part of the incision, and the spermatic cord was transformed into the abdominal wall. The hernia sac is discovered to completely overturned into the abdominal cavity, and the preperitoneal space was fully dissociated. The UMN3 mesh was placed in the free space, the medial side was 2cm longer than the pubic symphysis, and the lateral and upper sides were completely covered by the pubic muscle foramen. After the mesh was cemented and fixed by tissue glue spraying, the peritoneum was closed and sutured by barbed wire. The operation lasted for 4 hours and was completed at 13:55pm, and pneumoperitoneum was eliminated after the operation. The anesthesia received good effect with stable vital signs and smooth operation. Intraoperative bleeding was 10 ml and 600 ml of infusion.

After the operation, the patient was sent to the anesthesia recovery room for monitoring and observation for 20 minutes. Aldrete scored 10 points and was escorted out of the room into the ward. The patient was conscious on the way back to the ward. When he arrived at the ward, he suddenly had convulsions, pale face, and cardiac and respiratory arrest. Cardiopulmonary resuscitation was immediately given to the patient for about 15 minutes to recover his spontaneous breathing and heartbeat, with heart rate of 114 beats/min and blood pressure of 155/88mmHg. The anesthesiologist performed endotracheal intubation 16 minutes after cardiac arrest. A simple respirator was used to hold a ball for oxygen and was transferred to the intensive care unit. Diagnosis when enrolled in the intensive care unit: acute cerebrovascular disease? pulmonary embolism? After ICU admission, the patient was in mechanical ventilation with endotracheal intubation, with heart rate of 101 beats / min, blood pressure of 133 / 78mmHg, and blood oxygen saturation of 100%. Physical examination showed delirium, 2mm of double pupils. Besides, light reflection disappeared without voluntary movement of limbs, as a result, bilateral Babbitt signs were not elicited. The hospital performed symptomatic treatment such as ECG monitoring, oxygen inhalation, water and electricity balance, sedation and anti-convulsion.

In the afternoon of the second day after admission to ICU, the hospital completed the head CT, lung enhanced CT, CTA and other examinations, and the results showed that no obvious abnormalities were found in the intracranial. Low density filling defect was found in the right superior pulmonary artery and its branches, and superior pulmonary artery embolization was considered. It read changes of double pneumonia and localized atelectasis in both lower lobes, multiple emphysema in both lungs. The diagnosis of pulmonary embolism after inguinal hernia repair was confirmed. However, consultation in respiratory department considered thrombolysis as contraindication and anticoagulation was started at 19:30 PM. After symptomatic treatment, the patient was in a persistent vegetative state, and was eventually assessed as grade 1 disability with lifelong nursing dependence. In this regard, the patient's family believe that the misdiagnosis and improper treatment has provided by the hospital, a civil lawsuit and medical damage appraisal were brought to the court, and the hospital should bear certain civil liability for compensation.

### 3. Discussion

In clinical practice, it is generally believed that deep vein thrombosis is a common postoperative occurrence in the lower limbs with relatively hidden symptoms. Pulmonary embolism may suddenly lead to serious health damage or even death of patients. Although compared with traditional open surgery, laparoscopic hernia repair demonstrated the advantages of less trauma and faster postoperative recovery, and with the application and development of laparoscopic tension-free hernia repair, the adoption of the concept of preperitoneal space hernia repair as well as the application and development of laparoscopic hernia repair and other technologies, laparoscopic hernia repair in clinical practice is gaining increasing popularity. However, endoscopic surgery can be made to establish pneumoperitoneum under general anesthesia, and the surgical field and operating space are relatively narrow, which is prone to iatrogenic injury to the blood vessels in the surgical area. Deep vein thrombosis and sudden pulmonary embolism proved inevitable trend[7][8], which further deepen

the contradiction between doctors and patients and worsen the medical environment. In this regard, based on relevant legal and medical professional issues in this case, the following are discussed respectively.

### 3.1 Selection of surgical methods

The most effective treatment for inguinal hernia lies in surgery. According to the textbook of Surgery (The 9th Edition), the surgical methods are mainly summarized into three aspects: (1) Traditional hernia repair: The basic principle of surgery: ligation of the hernia sac at the high position, strengthening or repair of the inguinal canal wall. (2) Tension-free herniorrhaphy; (3) Laparoscopic hernia repair. At present, the common methods are respectively: Peritoneal preperitoneal repair through the abdominal cavity; Complete peritoneal repair; Intraperitoneal patch based repair; Simple hernia ring based repair.

Currently, laparoscopic laparoscopic hernia based repair is commonly used in clinical practice for transabdominal preperitoneal inguinal hernia repair (TAPP) and completely transperitoneal laparoscopic inguinal hernia repair (TEP)[9]. The advantages of TAPP are clear anatomical signs, large operation space, easy observation of patients' hernia contents, and full coverage of peritoneum by mesh, which can greatly reduce the risk of intestinal adhesion, obstruction and perforation. However, the disadvantages of this procedure present that the free area is larger than that of the inguinal hernia repair with internal abdominal net, resulting in a corresponding increase in injury to patients and a longer operation time. Moreover, the anterior peritoneum is removed in the abdominal cavity of patients, which may lead to severe complications such as visceral injury, blood accumulation in the scrotum and nerve pain. TEP is theoretically superior to peritoneal anterior inguinal hernia repair. It can be operated without entering the abdominal cavity of the patient, without causing damage to the abdominal cavity and viscera of the patient, and the mesh does not contact the patient's viscera, so the patient will not have intestinal adhesion after surgery.

However, the disadvantage of this procedure is that the small space for operation. Since there are no obvious anatomical signs, the hernia contents of patients fail to be directly observed, and the anatomical signs need to be gradually displayed, resulting in large damage to patients and long operation time. Therefore, laparoscopic inguinal hernia repair as a tension-free hernia repair method, has been widely used at home and abroad. However, there are various surgical methods of laparoscopic hernia repair, each with its own advantages and disadvantages, and the choice of surgical repair method for inguinal hernia is still with controversy[10].

Based on this, China's previous Tort Liability Law and the Civil Code and other civil laws have given clear legal provisions on how to choose the surgical method. As stipulated in Article 1219 of the Civil Code: medical personnel shall explain their illness and medical measures to the patients during diagnosis and treatment activities. In case of operation, special examination or special treatment, the medical personnel shall promptly explain the medical risks and alternative medical plans to the patients and obtain their explicit consent. If it is impossible or inappropriate to explain to the patient, medical personnel are required to explain to the patient's near relatives and obtain their explicit consent.

At present, the above provisions of China's civil laws on the notification way and legal responsibility of hospitals have still failed to attract enough attention from clinicians, especially the notification of alternative medical plans for surgical treatment. Even if the hospital and the patient communicate related before surgery, there is a lack of clear written communication evidence, wechat, video recording or audio recording evidence, resulting in the adverse legal status in the court litigation and technical appraisal, increasing the risk of losing the lawsuit or evaluating medical fault.

In this case, the medical institution lacks evidence of other alternative surgical methods except laparoscopic indirect hernia surgery, which is a typical feature of problems in clinical information. Due to the position of judicial appraisal and judicial trial, the patient was not informed of other alternative surgical treatment plans and their advantages and disadvantages in accordance with the provisions of the law, which affected the right of the patient to evaluate the advantages and disadvantages of different surgeries and participate in the selection of appropriate post-surgical methods based on the patient's own characteristics. As a result, it is difficult for the patient to accept the complications or other adverse results caused by the hospital's decision to implement the surgical method, which has a causal effect on the level of legal evaluation.

### 3.2 Preoperative discussion system

Whether the preoperative discussion system can affect the quality of surgery has always been an important topic in clinical research. Academician Li Jieshou and academician Wu Jiping, famous medical experts in China in the last century, believed that preoperative discussion determines the success of surgery, and the preoperative discussion system should be earnestly implemented [11][12]. Unfortunately, so far in clinical practice, the implementation and implementation of preoperative discussion system received unsatisfactory results. The former Ministry of Health issued the Basic Standards for Writing Medical Records, which defined the preoperative discussion record as the discussion on the proposed surgical methods, possible problems and countermeasures under the auspices of superior physicians before surgery due to the serious

condition of patients or the difficulty of surgery. Therefore, whether to hold preoperative discussion is quite flexible and arbitrary in clinical practice.

How to judge the severity of the disease or the difficulty of the operation varies from different levels of hospitals, hospitals in different regions and different surgeons. Under the influence of the "Basic Standards for Writing Medical Records", many clinical personnel think that preoperative discussion is only a working system, and there is no clear causal relationship with the quality of surgery and the emergence of simultaneous development of surgery. In this case, medical personnel of the hospital clearly stated in the lawsuit that preoperative discussion is only a written work and procedural system, which proves to have no clear causal relationship to the improvement and prevention of surgical quality and surgical complications. The evaluation of the impact of lack of preoperative discussion on the quality of surgery is like the characteristics of "word prison".

Virtually, in 2018, the National Health Commission began to push forward the 18 core systems for the safety and quality of medical institutions, and the preoperative discussion system is one of them. Different from the requirements of the "Basic Standards for Writing Medical Records", the National Health Commission has made more strict and clear provisions on the preoperative discussion system, requiring all inpatients to have preoperative discussion except for emergency surgery, so as to improve surgical safety and perioperative management quality.

What is valuable is that some clinical studies on the value of perioperative preoperative discussion have shown [13] that standardized preoperative discussion and improve the quality of preoperative discussion, the incidence of surgical complications and patient mortality decreased, suggesting that strengthening preoperative discussion quality control is an effective measure to improve surgical quality and improve surgical safety.

In this case, the hospital lacked preoperative discussion, and the laparoscopic oblique hernia operation lasted for four hours without any specific measures to prevent deep venous thrombosis. There are difficulty for record and surgery to describe bowel adhesion and separation as well as for other complications such as vascular injury, bowel injury description and rescue records. Patients with preoperative and intraoperative for surgery may encounter problems. Besides, improvement and preventive measures are given sufficient preparation and understanding, no doubt increased the incidence of surgical complications.

### **3.3 Normative evaluation of preoperative examination**

As an important clinical diagnosis and treatment activity in perioperative period, preoperative examination has always been given priority by clinical medical personnel and should be fully reflected in the preoperative summary. But for the standardization of preoperative examination, clinical medical personnel failed to give necessary attention. Preoperative examination items are usually determined in accordance with habitual thinking and professional feeling, which sometimes omits important examination and affects preoperative relevant score.

Based on current textbooks, clinical diagnosis and treatment guidelines or expert consensus, clinical examination methods and diagnosis methods of diseases are introduced in detail, but there is basically no clear items on preoperative examination, auxiliary examination. Besides, further examination need to be determined according to the history, physical examination and results of necessary examination items. Therefore, the standardization of preoperative examination should arouse the attention of clinical medical personnel. In this regard, the disease clinical pathway promoted by the former Ministry of Health and the current National Health Commission has made corresponding provisions, which has played a good guiding role in the standardization of preoperative examination of clinical surgical treatment activities in China.

"Clinical pathway management" is a beacon to a disease. The medical staff in hospitals must follow the diagnosis and treatment model, so that patients can receive standardized and rational clinical examination, surgery, treatment, nursing and other standardized medical services from admission to discharge according to the model, while controlling medical costs and ensuring and improving medical quality. Since 2009, the total number of clinical pathways issued by the NHC has reached 1,212, covering more than 30 clinical specialties, basically covering all common and multiple diseases in clinical practice, and basically meeting the needs of clinical diagnosis and treatment. According to the "Requirements of Clinical Pathway For Indirect Inguinal Hernia", chest radiography should be performed as stipulated in the preoperative examination items, and other lung imaging examinations such as lung CT should be determined according to the examination results.

In this case, the hospital performed routine blood examination, liver and kidney function, coagulation function and electrocardiogram examination after admission, but chest radiography failed to be performed. After pulmonary embolism occurred after surgery, lung CT examination showed large pulmonary bullae and atelectasis in the lower lobe of both lungs. Therefore, the hospital failed to improve the preoperative chest radiography or lung CT examination, which had a significant impact on the preoperative thrombosis evaluation results. According to Caprini score, the patient without chest radiography or lung CT examination only gained 2 points, which belongs to low risk, and simple mechanical embolization can meet the



requirements of clinical guidelines.

However, if chest radiography or lung CT examination is improved, the patient has obvious pathological changes in lung tissue, and the score can reach 3 points, which is a medium-high risk and requires anticoagulant preventive treatment before surgery. The different measures for preventing deep venous thrombosis before operation will have different effects on the adverse outcome of pulmonary embolism after operation.

### **3.4 Laparoscopic oblique hernia surgery and deep venous thrombosis**

Inguinal hernia based repair can produce a variety of adverse complications or treatment results, and iatrogenic vascular injury has been the major complication of clinical concern in the past. In recent years, with the gradual increase of complications of deep vein thrombosis and pulmonary embolism, clinical studies have recognized that deep vein thrombosis and pulmonary embolism have become one of the potential and very dangerous serious complications of inguinal hernia patients. Existing clinical studies suggest that general anesthesia and pneumoperitoneum are important factors for increasing deep venous thrombosis in laparoscopic inguinal hernia surgery. However, elderly patients with more basic diseases, complicated hemodynamics, surgical operations or mesh placement can affect lower limb venous return, which can be the inducement of deep venous thrombosis. Combined with the characteristics of pneumoperitoneum established by laparoscopy, surgical time should also be considered as one of the possible causes of deep venous thrombosis.

Existing clinical literature suggests that the duration for laparoscopic abdominal femoral hernia surgery lasts generally 1-2 hours, and duration can be compressed to less than one hour by skilled patients. Wang Bao et al.[14] reported that the duration of 70 cases of laparoscopic inguinal hernia surgery ranged from 33 to 58min (average  $41.3\pm 5.2$ min). Li Shaojie Jie et al.[7]reported that duration for 1002 cases of laparoscopic inguinal hernia surgery ranged between 20-208min (average  $72.7\pm 31.1$ min). Research by Cai xiaoyong et al. [15] showed that duration for laparoscopic intraabdominal patch covering (IPOM) lasted 38~160min, with one side of 55min and 106min on both sides. The surgical duration of TAPP of peritoneal preperitoneal repair was 52~136min, and that of total extraperitoneal hernia repair (TEP) reached 37~186min.

Yin Binwen et al. [16] reported that the surgical duration of 95 cases of laparoscopic transperitoneal preperitoneal hernia repair was within the range of 70min (average  $40\pm 130$ min). Yan Tao et al.[17] reported that the surgical duration of laparoscopic peritoneal preperitoneal repair in 200 patients was  $39.1\pm 10.5$ . In this case, the TAPP operation lasted for 4 hours, far beyond duration range shown by clinical evidence-based medicine, and no measures were taken to prevent thrombosis during operation. Such a long period of pneumoperitoneum (Set abdominal pressure of 12mmH) and operation at the surgical site can undoubtedly become risk factors for deep venous thrombosis. Therefore, one of the effective measures for deep venous thrombosis secondary to inguinal hernia surgery should be to improve the familiarity and skills of anatomical structure and operation, effectively control the operation time of less than 2 hours, and actively or passively move the lower limbs intermittently during the operation.

### **3.5 Rescue, treatment, examination and evaluation and thrombolytic treatment of cardiopulmonary arrest caused by pulmonary thromboembolism**

Some patients with pulmonary thromboembolism (referred to as pulmonary embolism) can be characterized by cardiac arrest, shock, syncope, severe dyspnea and hypoxemia difficult to correct, called fatal pulmonary embolism, which is an extremely dangerous and critical disease, with a fatality rate of 65%~95% [18]

Therefore, early diagnosis and timely administration of comprehensive therapeutic measures including thrombolysis are the key to improve the prognosis. Unfortunately, there is no consensus on the diagnosis and treatment procedures and treatment strategies of cardiopulmonary arrest caused by suspected pulmonary embolism. It is still controversial whether to conduct conventional thrombolytic therapy, and various international guidelines have not made clear recommendations on routine or empirical thrombolysis in such patients. In clinical practice, patients complicated with cardiac arrest have a sudden onset and are difficult to conduct CTPA examinations due to their critical condition It is a great challenge for clinicians to make urgent decisions about whether performing thrombolysis therapy at emergency CPR.

However, it has also been found in clinical studies[19] that the main cause of resuscitation difficulties in patients with cardiac arrest is the failure to remove the primary factors leading to cardiac arrest, such as severe PTE and AMI, which clinically account for about 70% of non-traumatic cardiac arrest. As such patients, on most occasions, failed to be diagnosed in time for effective treatment, and thus leading to death. Some authors reported [20] that performed immediate angiography in successfully resuscitated cardiac arrest patients, and found that 48% had acute coronary artery blockage, suggesting that these patients also had an indication for thrombolytic therapy. Moreover, the incidence of intracranial hemorrhage in PTE thrombolytic therapy is about 1.9%. Compared with the high mortality of these patients, empirical thrombolytic therapy obviously witnesses a better risk-benefit ratio. Prospective studies have reported [21] that thrombolytic therapy and heparin

are safe and has significantly improved prognosis in patients with non-traumatic cardiac arrest who fail to succeed after 15min of routine CPR.

It is worth pointing out that CPR is listed as a relative contraindication of thrombolytic therapy in the previous clinical guidelines. However, CPR is no longer listed as the category in the 2018 edition of Chinese Guidelines for the Diagnosis and Treatment of Pulmonary Embolism[22]. In recent years, In Chinese clinical medicine, cases of cardiopulmonary arrest with the first characteristic were suspected as pulmonary embolism, and successful rescue by active thrombolytic therapy was reported successively[23][24], which further supported active assessment of primary causes (including pulmonary embolism and acute myocardial infarction) for such patients, and docent-patient communication about the risks and benefits of thrombolytic therapy. On this basis, early implementation of empirical thrombolytic therapy is also one of the measures that should be considered and taken in clinical rescue treatment.

#### 4. Conclusion

In recent years, laparoscopic inguinal hernia repair surgery at home and abroad has developed rapidly, and the number of operations has increased greatly, and the effect of surgical treatment has been more and more reported and affirmed. Although laparoscopic inguinal hernia repair has fewer complications, less postoperative pain, faster return to normal activities, less chronic pain and numbness, but also have some disadvantages example higher technical standards, more difficult operation, longer learning curve, identification of anatomical structures is completely different from open surgery, and surgery operation need to be under general anesthesia, etc. Therefore, domestic and foreign attention to the quality control of laparoscopic inguinal hernia surgery. The study in this paper also shows that the preoperative discussion, preoperative examination and preoperative notification in clinical laparoscopic inguinal hernia should be make great attention, and form an institutionalized and normative working mode, itself is to improve the quality of inguinal hernia operation, in the operation time, reduce surgical complications and avoid medical disputes.

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