Chirurgia laparoscopica: eventi avversi e responsabilità del chirurgo

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Master di II livello in «Medicina legale: il danno alla persona nei suoi aspetti medico-legali e giuridici»
I Edizione
“adverse event”

“... any state or event unfavourable to the patient’s health, that arose during admission or within 30 days after discharge, that either causes unintentional injury or requires additional treatment”
~ 14000 decessi in Italia;

~98000 decessi in USA (8 causa di morte);

10,9% chirurgia generale;

60% errori evitabili;

38% sala operatoria;

4% spesa sanitaria totale
Patterns of technical error among surgical malpractice claims: an analysis of strategies to prevent injury to surgical patients.

Regenbogen S. 2007

↑ surgical adverse events involve technical errors.
65% were linked to manual error; 9% to errors in judgment; 26% to both.

Technical error:
Patient-related complexities 61% (emergency, difficult or unexpected anatomy and previous surgery)
Technology or system failure 21%
“...increased complexity of laparoscopic surgery requires much longer pneumoperitoneum time and this raises concerns about the adverse effects of prolonged gas insufflation such as cardiovascular, respiratory and renal failures caused by a direct increase of I.A.P. and sympathetically mediated vasoconstriction.”
Carbon dioxide embolism during pneumoperitoneum for laparoscopic surgery: a case report.

Smith HJ. 2011

Portal vein thrombosis and pulmonary artery thromboembolism after laparoscopic colectomy.

Shinozaki M. 2011


Maalouf M. 2008
Physiologic changes during laparoscopy

Pneumoperitoneum; $CO_2$ absorption

- Miocardial ischemia
- Respiratory acidosis
- Blood flow alterations

Organ disfunction / failure
Thromboembolic complication in L.S.

pathophysiologica changes (↑ abdominal pressure, -- Trendelenburg position)

effects on venous flow;
activation of hemostatic system

Laparoscopy associated mesenteric vascular complications.

Richmond BK. 2010
Risk of bleeding associated with use of systemic thromboembolic prophylaxis during laparoscopic cholecystectomy.

Person G. 2012

1) P.T.E. (D.V.T. 0,03%, P.E. 0,06%, both 0,2%);
2) Bleeding complication (per-op. 1,9%; post-op. 1,4%);
3) Antithrombotic medication (post-operative)

«Prophylaxis thromboembolic is not as harmless as often considered»
La possibilità di stratificare il rischio tromboembolico ed emorragico dei pazienti rappresenta il punto chiave di una corretta profilassi antitrombotica;

In assenza di indicatori del rischio individuale, è necessario applicare una adeguata forma di profilassi antitrombotica a seconda della classe di rischio cui appartiene il paziente;

La miglior decisione deve basarsi sulla combinazione delle raccomandazioni delle LG con il giudizio clinico.

Famulari C. 2010
Laparoscopy in patients with prior surgery: result of the blind approach.

Lecuru F. 2001

30-50% of complications take place during the surgical access (vascular and bowel injuries, incision complication)

prior abdominal surgery, thin women

no longer a controindication to laparoscopy; operator skill.
Abdominal wall hematoma after laparoscopic surgery: early treatment with selective arterial transcatheter embolization.

Màrtin-Màlogan A. 2007

Site of trocar insertion
↑ bleeding
Hemoperitoneum, haematoma abdominal wall
Abdominal aortic injury as a complication of laparoscopic cholecystectomy.

Alcazar MT 2004

“During laparoscopic surgery usually occurs upon introduction of trocars for initiating pneumoperitoneum. The technique must be performed correctly and monitored properly to assure early detection of adverse events associated with high mortality.”
Laparoscopic cholecystectomy on a previously operated abdomen.

Bouasker J 2010

“The existence of an upper umbilical scar is related to a greater number of adhesions, an increased risk of operative complications, a greater conversion rate, a prolonged operating time and a longer hospital stay.... post-operative complications are similar”
Lesioni iatrogene della via biliare principale

Lesioni iatrogene V.B.P.
(90% durante colecistectomia)

- Anni '80 frequenza stabile 0,15%
- Anni '90 rapida diffusione approccio laparoscopico (mezzi di informazione, industria, pazienti, chirurghi)

«gold standard»

Frequenza 0,49%- 0,55%

S.I.C. 2002
«Non sempre le complicanze possono essere addebitate alla laparoscopia ma piuttosto alla sua non corretta utilizzazione sia nelle indicazioni che nella tecnica»

Fattori di rischio:

• Esperienza operatore 0,34% - 0,18% - 0,08%
• (80% chirurghi in formazione)
• Anomalie anatomiche 6%;
• Alterazioni anatomiche.

S.I.C. 2002

Lesioni maggiori (sezione e stenosi) 0,25%- 0.74%
Lesioni minori (deiscenza cistico, dotti per. ) 0,28- 1,7%
«curva fisiologica di apprendimento»
(n° interventi, conversione, tecnica operatoria)
«incidenza media volume di attività»
• Fistole biliari post-colecistectomia
  – 1° posto azioni giudiziarie per negligenza
  – 6° posto per riconoscimenti assicurativi
  – Procedimenti medico-legali (C.L. +20 volte)

S.I.C. 2002
Aspetti medico-legali: considerazioni

Condotta ritenuta colposa

- Consenso informato «non adeguato»
- fasi atto terapeutico (contro indicazione C.L.)
- Gestione post-operatoria
- Mancata indicazione reintervento

S.I.C. 2002
Dropped gallstones during laparoscopic cholecystectomy: the consequences.

Tumer AR. 2005

- gallstone spillage 3.8%
- complications for retained stones 12%

“The surgeon should not hesitate to record the events and inform the patient about the spillage of the stones and possible consequences.”
«... are being reported with increasing frequency. Therefore, it is important to use tools and techniques that prevent lacerations of the gallbladder and involve retrieval of spilled gallstones.»
Iatrogenic biliary ducts lesions after laparoscopic cholecystectomy: a medical technical error or a therapeutic failure in a routinely performed procedure. A medico-legal evaluation of selected cases.

Chowaniec C. 2007

- “...procedures performed by surgeons with insufficient operator skills”

- “...the medico-legal evaluation of “biliary damage” is very difficult”
Urological complications following inguinal hernioplasty.

Gulino G. 2012

“extensive laparoscopic procedures (due to the need of learning curve) have increased the risk of vas damage and infertility in young patients candidate to hernioplasty.”

per-oper: bladder or spermatic cord damage.

post-oper immediate: ischaemic or bacterial orchitis, hydrocele or scrotal haematoma.

Post-oper long-term: chronic orchialgia, testis atrophy, sexual dysfunction and infertility.
Nowadays we can undoubtedly maintain that laparoscopic trans- or extraperitoneal techniques have become a gold-standard surgical treatment in case of recurrent bilateral groin hernias.
“...laparoscopic surgery vs open surgery are equivalent with a potential reduction in complications and hospital stay.”

“... laparoscopic surgery performed by appropriately experienced surgeons in the elective setting may be safe and feasible.”
• Major complications 11%; pancreatic fistulae 23%

• Risk score: BMI >27, pancreatic specimen length >8 cm, EBL ≥ 150 mL
Previous abdominal operations do not affect the outcomes of laparoscopic colorectal surgery.

Law W 2005

“The presence of prior surgery does not affect the operating time or blood loss of patients undergoing laparoscopic colorectal surgery. The postoperative outcomes are not worse. Previous abdominal surgery should not be considered as a contraindication for laparoscopic approach.”
The role of laparoscopy in emergency abdominal surgery

- Acute emergency situations often pose a diagnostic challenge to the surgeon.
- The diagnostic accuracy of laparoscopy is reported with a rate of 89%-100% in literature.
- The absolute and relative contraindications to laparoscopy are the same as for elective procedures.
The results of several experiences show the feasibility of D.L. in abdominal emergencies with acceptable morbidity (0-24%) and mortality (0-4.6%) comparable with those reported for OP". 
The evidence available to date clearly demonstrates the superiority of laparoscopic approach in various emergency situations.

Grade A: Cholecystitis, Gastro-duodenal perforated ulcers, appendicitis, gynecological disorders, NSAP.

Grade B: abdominal trauma, pancreatitis.

Grade C: small bowel obstruction, acute diverticulitis, incarcerated hernia, mesenteric ischemia.
• **Approccio laparoscopico alla peritonite**
  Famulari C. 2003 Congr. Naz. SICUT

• **Attualità nel trattamento delle peritoniti**
  Famulari C. 2003 Congresso SIC 2003

• **MIS and Peritonitis**
  Crescenti 2000
Presupposing appropriate perioperative measures and surgical technique, there is no reason to controindicate pneumoperitoneum in patients with peritonitis...
...insufflation does not facilitate hematogenous dissemination of bacteria from intraperitoneal sepsis in the animal model.

Dugue 1995

...laparoscopic CO$_2$ pneumoperitoneum does not aggravate bacteremia or metabolic and hemodynamic disturbances induced by bacterial peritonitis.

Collet 2000

...conventional and laparoscopic lavage reduce inflammation.

Pross 2002
CONTROINDICAZIONI ASSOLUTE

• Peritoniti stercoracee (Hinchey 4)
• Peritoniti generalizzate neoplastiche
  • Distensione intestinale massiva
• Insufficienza cardiorespiratoria grave
  • Instabilità emodinamica
  • Shock settico conclamato
  • Gravi coagulopatie
L'entusiasmo con cui la chirurgia miniinvasiva è dai più accettata non è certamente frutto del fascino delle "novità", ma ormai è giustificato da dati oggettivi che dimostrano che la tecnica consente di ottemperare in modo quasi ottimale ai principi basilari del trattamento delle peritoniti enunciati da Kirschner già nel 1926.

Famulari 2003
• Trattamento videolaparoscopico della colecistite acuta in età geriatrica.
  Famulari C. 2001

• Il trattamento videolaparoscopico della colecistite acuta
  Famulari C. 2005
Acute gallstone cholecystitis in the elderly: treatment with emergency ultrasonographic percutaneous cholecystostomy and interval laparoscopic cholecystectomy.

Macrì A. 2005
“laparoscopic emergency is feasible, effective, safe and beneficial for patients to be a part of common surgical practice as adequate training is obtained and proper preparation observed when more advanced procedures are attempted in critically ill patients”
“Excellent agreement of procedural errors can be achieved by carefully defining and training recognition of targeted events”.

“...define behaviours leading to adverse clinical outcomes.”
“...the hope is that awareness of causes and mechanisms of errors may reduce incidence in clinical practice for the final benefit of the patients.”

“adverse events in laparoscopy”
“laparoscopy is a complex technique where incidents related to equipment failure/malfunction commonly occur.”

“laparoscopy require the use of highly technical equipment and familiarity with its function demands more attention than does simple O.S.

surgical check-list for safety measure has decreased the morbility and mortality rates
...the revolutionary development of MIS has fused new technology and practice of medicine to achieve remarkable benefits in terms of patients recovery.

- need for training and credentialing of surgeons in laparoscopy cannot be ignored
- only a valid and reliable method of assessment can determine technical competence

Laparoscopic simulator
Surgery places high demands for quick decision-making and for accomplished technical skills of the surgical team.

- Impact of acute stress on surgical performance
  - Experienced surgeons
  - Pre-briefing, check-list procedure
Risk-sensitive events during laparoscopic cholecystectomy: the influence of the integrated operating room and a preoperative checklist tool.

Buzink S. 2010

- “laparoscopic surgery had, initially, a relatively large number of complications and adverse events”
- “laparoscopic surgery requires a different set of skills and the surgical team is more dependent on technology“

“Patient SAFETY”
CHECK-LIST

- significantly incidents (nearly 50%)
- loss of time (31%), mortality (1.5% to 0.8%)

«SURGICAL ENVIRONMENT»

Communication between all members of team with cross-verification

«Dependence on technical equipment during laparoscopy is a very frequent source of potentially dangerous adverse events and loss of time»

Romain B. 2012
The problems originate from an insufficient pre-op. information of the patient

- Expert opinions are an instructive source of learning about possibly avoidable errors
- Knowledge contribute to the prevention of the recurrence of mistakes
“...the profile of the surgeon and the surgical team is still a crucial issue. A well-trained and experienced surgeon together with a well-trained team is a necessary prerequisite for diagnostic and therapeutic laparoscopy”