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The critical view of safety during keyhole surgical gallbladder removal: Strasberg method yes or no? An Italian multicentre study

Submission date 29/01/2020	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 31/01/2020	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 31/01/2020	**Condition category** Digestive System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Keyhole surgery for gall bladder removal (laparoscopic cholecystectomy) is currently and worldwide considered the gold standard for the treatment of gallbladder stones. Since its introduction, in the early 1990s, this procedure has gained a remarkable consensus until becoming a routine surgical procedure. However, this procedure comes with an increased incidence of bile duct injuries (BDI), compared to open cholecystectomy (OC): 0.3% and 0.8% vs 0.2%. Strasberg introduced in 1995 the "Critical View of Safety" (CVS) to promote the recognition of the gallbladder elements in order to reduce the risk of BDI and to avoid mistakes due to anatomical alterations and altered visual perception.
The SYoN (Strasberg Yes or No) study is a multicentre Italian observational prospective cohort study, performed by collecting and analysing clinical data of patients managed in 30 Italian surgical departments, affiliated with the Italian Digestive Pathology Society (SIPAD), over a study period of 2 years. The study was conducted prospectively with the insertion of patients on a national database whose data, however, were retrospectively collected after patient discharge not to influence patient management. This prospective study aimed to assess the impact of the correct application of CVS principles during LC on the incidence of postoperative complications, such as BDI and bleeding.

Who can participate?
Adult patients treated with Laparoscopic Cholecystectomy at one of the study sites.

What does the study involve?
Patients will be treated as usual. The data will be collected after patient discharge not to influence patient management. Patients receive the most suitable surgical treatment based on their clinical conditions, the preoperative study, and the intraoperative findings.

What are the possible benefits and risks of participating?
The study doesn’t influence the management of patients causing any risk for participating but

aiming to analyse the effective application of CVS in the current surgical practice. This study could be potentially useful to encourage the safest management in case of CVS not applicable such as open conversion and subtotal cholecystectomy.

Where is the study run from?
Department of Biomedical Sciences and Human Oncology - Unit of General Surgery "V. Bonomo" University Medical School of Bari (Italy)

When is the study starting and how long is it expected to run for?
March 2017 to March 2019

Who is funding the study?
Universita degli Studi di Bari Aldo Moro (Italy)

Who is the main contact?
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Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Uniba-5674

Study information

Scientific Title
The impact of the correct application of critical view of safety (CVS) principles during laparoscopic cholecystectomy on the incidence of postoperative complications

Acronym
SYoN

Study objectives
The CVS is the safest technique for recognizing the elements of the Calot triangle and in preventing intra-operative complications (iatrogenic lesions and perioperative bleeding).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/10/2018, Ethics Committee of the University of Bari (Policlinico di Bari - P.zza G. Cesare n. 11, Bari- 70124, Italy; +39 (0)80 5593399; comitatoetico@policlinico.ba.it), ref: 5674

Study design
Multicentre observational prospective cohort study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute cholecystitis and cholelithiasis

Interventions
All members of SIPAD society (Italian Digestive Pathology Society) will be invited by email to participate in the study through an online questionnaire. The questionnaire (23 questions divided into six forms) examines the preoperative workup, the laparoscopic training of the first surgeon, the intraoperative management of the patient, and the post-operative phase concerning any BDI and peri-operative bleeding.

Patients submitted to emergency LC for acute cholecystitis, elective LC for chronic pathologies, and patients treated with LC during other major laparoscopic surgeries are eligible for inclusion if a proper preoperative examination is conducted by the operating surgeon.

In case of declared CVS, the surgeon is asked to judge personally at the end of the procedure if the isolation of the elements is performed according to all the points described by Strasberg, and subsequently to attach an iconographic item (Video or "Doublet Photography") in case of dissection of the Calot triangle with CVS.

During compilation, the iconographic documentation (video or photo) is sent to a dedicated encrypted email address indicating the date of the surgery, the patient's initials, the date of birth and the recruiting centre.

Data collection, compiled by the recruiting centre, is centrally recorded into an electronic database of the data manager (SIPAD), which also ensured the blinding of the lead operator. Finally, an expert surgeon with high skill in hepatobiliary and laparoscopic surgery will review, as external auditor, all the iconographic documentation to establish the strict adherence of the declared manoeuvre with the three principles of the CVS of Strasberg.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Measured using patient records
1. Rate of Bile Duct Injuries
2. Rate of bleeding

Key secondary outcome(s))
Measured using patient records:
1. Duration of surgery in minutes
2. Length of a hospital stay
3. Operator-related risk factors
4. Patient-related risk factors

Completion date
01/03/2019

Eligibility

Key inclusion criteria

1. Patients submitted to emergency Laparoscopic Cholecystectomy for acute cholecystitis
2. Patients submitted to elective Laparoscopic Cholecystectomy for cholelitiasis
3. Patients treated with Laparoscopic Cholecystectomy during other major laparoscopic surgeries

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients submitted to open cholecystectomy
2. Patients submitted to laparoscopy converted to open surgery
3. Patients submitted to surgery with evidence of malignant pathologies of the gallbladder

Date of first enrolment
01/03/2017

Date of final enrolment
01/03/2019

Locations

Countries of recruitment
Italy

Study participating centre
University Medical School of Bari
Department of Biomedical Sciences and Human Oncology - Unit of General Surgery V. Bonomo
Piazza G. Cesare, 11
Bari
Italy
70124

Study participating centre
Sant' Andrea Hospital
Department of General Surgery
Via Vittorio Veneto, 197
La Spezia

Italy
19121

Study participating centre
San Donato Hospital
Department of Surgery, Division of General Surgery
via Pietro Nenni 20-22
Arezzo
Italy
52100

Study participating centre
Cles Hospital
Department of Surgery, Division of General Surgery
via Degasperi 31
Cles
Italy
38023

Study participating centre
Sant' Elena Hospital
Department of Surgery, Division of General Surgery
Via Guglielmo Marconi, 160
Quartu Sant'Elena
Italy
09045

Study participating centre
San Martino Hospital & National Cancer Institute
Surgery Unit 1
Largo Rosanna Benzi, 10
Genova
Italy
16132

Study participating centre
Federico II University of Naples
Department of Clinical Medicine and Surgery
Via Sergio Pansini, 5

Naples
Italy
80131

Study participating centre
Parma University Hospital
Emergency Surgery Department
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Italy
43126

Study participating centre
Policlinico San Martino IRCCS
Department of Surgery
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16132

Study participating centre
San Bonifacio (ULSS9 Scaligera)
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San Bonifacio
Italy
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Study participating centre
Hospital of Brescia
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25128

Study participating centre
ASST Nord Milano
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20099

Study participating centre
IRCCS policlinico San Matteo
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Viale Camillo Golgi, 19
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27100

Study participating centre
Department of Surgery, Villa Esther
Via dei Due Principati, 169,
Avellino AV
Italy
83100

Study participating centre
ASST FBF Sacco
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Study participating centre
Hospital of Ponderano
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Study participating centre
Hospital "Sant'Elia"
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Via Luigi Russo, 6
Caltanissetta
Italy
93100

Study participating centre
Hospital Vanvitelli
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Piazza Luigi Miraglia, 2
Naples
Italy
80138

Study participating centre
Hospital of Prato
Department of Surgery
Via Suor Niccolina Infermiera, 20/22
Prato
Italy
59100

Study participating centre
University Medical School "A. Moro" of Bari
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Piazza G. Cesare, 11
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Italy
70124

Study participating centre
University of Palermo, Policlinico P. Giaccone
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90127

Sponsor information

Organisation
University of Bari Aldo Moro

ROR
https://ror.org/027ynra39

Funder(s)

Funder type
University/education

Funder Name
Universita degli Studi di Bari Aldo Moro

Alternative Name(s)
University of Bari Aldo Moro

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Italy

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes