

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

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<b>Registration date</b> 31/01/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 31/01/2020	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?

Prof. Mario Testini (scientific)

mario.testini@uniba.it

Dr Lucia Sgaramella (public)

ilaria.sgaram@gmail.com

### **Study website**

[https://www.sipad.it/area\\_04\\_pubblicazioni/protocollo\\_testini.aspx](https://www.sipad.it/area_04_pubblicazioni/protocollo_testini.aspx)

## **Contact information**

### **Type(s)**

Scientific

### **Contact name**

Prof Mario Testini

### **ORCID ID**

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### **Type(s)**

Public

### **Contact name**

Dr Lucia Sgaramella

### **ORCID ID**

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**Additional identifiers****EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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

**Secondary study design**

Cohort study

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**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 measure**

Measured using patient records

1. Rate of Bile Duct Injuries
2. Rate of bleeding

**Secondary outcome measures**

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

**Overall study start date**

01/01/2017

**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 cholelithiasis
3. Patients treated with Laparoscopic Cholecystectomy during other major laparoscopic surgeries

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

650

**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  
Viale Antonio Gramsci, 14  
Parma  
Italy  
43126

**Study participating centre**

**Policlinico San Martino IRCCS**

Department of Surgery  
Largo Rosanna Benzi, 10  
Genova  
Italy  
16132

**Study participating centre**

**San Bonifacio (ULSS9 Scaligera)**

Department of Surgery  
Via Circonvallazione, 1  
San Bonifacio  
Italy  
37047

**Study participating centre**

**Hospital of Brescia**  
Department of Surgery  
Via Bezzecca, 10  
Brescia  
Italy  
25128

**Study participating centre**  
**ASST Nord Milano**  
Department of Surgery  
Viale Giacomo Matteotti, 83  
Sesto San Giovanni  
Italy  
20099

**Study participating centre**  
**IRCCS policlinico San Matteo**  
Department of Surgery  
Viale Camillo Golgi, 19  
Pavia  
Italy  
27100

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

**Study participating centre**  
**ASST FBF Sacco**  
Department of Surgery  
Via G.B Grassi, 74  
Milano  
Italy  
20157

**Study participating centre**  
**Hospital of Ponderano**  
Department of Surgery



Via dei Ponderanesi, 2  
Biella  
Italy  
13875

**Study participating centre**

**Hospital "Sant'Elia"**

Department of surgery

Via Luigi Russo, 6

Caltanissetta

Italy

93100

**Study participating centre**

**Hospital Vanvitelli**

Department Of Surgery

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**

Unit of Laparoscopic Surgery, Department of Emergency and Organ Transplantation

Piazza G. Cesare, 11

Bari

Italy

70124

**Study participating centre**

**University of Palermo, Policlinico P. Giaccone**

Department of Surgical, Oncological and Oral Sciences (Di. Chir. On. S.)

Via Liborio Giuffr  5

Palermo  
Italy  
90127

## Sponsor information

### Organisation

University of Bari Aldo Moro

### Sponsor details

Unit of General Surgery "V. Bonomo"  
Department of Biomedical Sciences and Human Oncology  
University Medical School "Aldo Moro" of Bari  
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### Sponsor type

Hospital/treatment centre

### Website

<http://www.uniba.it/english-version>

### 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**

**Publication and dissemination plan**

Publication in Surgical Endoscopy.

**Intention to publish date**

01/11/2020

**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