

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 31/01/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 31/01/2020	Condition category 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)

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Dr Lucia Sgaramella (public)

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Study website

https://www.sipad.it/area_04_pubblicazioni/protocollo_testini.aspx

Contact information

Type(s)

Scientific

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Public

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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

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Department of Biomedical Sciences and Human Oncology
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70124
+39 3355370914
mario.testini@uniba.it

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