The role of robotic surgery in emergency setting

Study Protocol

Title:	The role of robotic surgery in emergency setting
Sponsor:	World Society of Emergency Surgery (WSES), Clinical Robotic Surgery Association (CRSA)
Principal investigators	Marco Milone, MD, PhD, FACS Associate Professor of Surgery; Fausto Catena, MD, PhD, Chief of General and Emergency Surgery Unit; Luca Morelli, MD, FACS, FASCRS, Associate Professor of Surgery
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Rationale	Robotic surgery has progressively gained acceptance in several surgical fields, being routinely used for elective interventions1-3. The issue regarding the role of robotic surgery for emergency procedures remains open. Few studies have been published regarding the applications of robotics for emergency general surgery procedures; they were reviewed and discussed in the 2021 WSES position paper4. Studies on colorectal surgery, hiatal hernia surgery, bariatric surgery, gallbladder surgery, and abdominal wall surgery were included and statements proposed. The experts recommended a strict patient selection, an adequate training of the operating surgical team and an improvement of the accessibility of the robotic platforms. We propose this prospective study to better define the application of robotic surgery in an emergency setting, evaluating the intraoperative and

	postoperative outcomes, trying to understand the role of the robotic platform in the management of emergency situations.
Aims of the study	Evaluate safe and feasibility of robotic surgery in emergency setting.
Clinical Phase:	Observational, prospective, multicentre
List of partecipating Centres	**TBD**
Study design:	**Data of clinically stable patients who underwent robotic surgery in emergency setting will be prospectively analysed**. The pathologies that will mainly be taken into consideration will be acute diverticulitis, acute cholecystitis and obstructed hernias. The Hinchey classification will be used to describe the degree of acute diverticulitis5, and the 2018 Tokyo guidelines will be used to describe the degree of acute cholecystitis6. Patients with other surgical pathologies may also be enrolled in the study as long as they are treated in robotic surgery in emergency setting. **Data relating to the operating theatre team and the surgical instruments used will be collected in order to conduct a cost analysis.** Data will be collected in a designated database.
Inclusion Criteria	• Age > 18 years old • Clinically stable patients with disease requiring emergency surgical treatment • Intervention performed in robotic surgery • Capability of giving valid informed consent
Exclusion Criteria	• Age < 18 years old • Intervention performed in open or laparoscopic surgery • Elective surgery • Clinically unstable patients • Inability of giving valid informed consent
Variables under study:	**Patient-related:** • Sex (Male/Female) • Age (years) • BMI (kg/m2)

	• aCCI (age-adjusted Charlson comorbidity index) • Previous abdominal surgery (yes/no) **Disease-related:** • Acute diverticulitis / Acute cholecystitis / Obstructed Hernia / Other (specify) • Severity grading of diverticulitis according to Hinchey classification (1a / 1b / 2 / 3 / 4) (*if applicable*) • Severity grading of cholecystitis according to Tokyo guidelines (I / II / III)(if applicable) • Site of hernia (*if applicable*) **Treatment-related:** • Amount of robotic surgeries performed in the institution • Expertise of surgeon (number of robotic surgeries performed) • Type of procedure performed • Time of intervention (hh:mm AM/PM) • Operative time (min) • Intraoperative complications (Bleeding or damage to major vessels / Organ injuries requiring reconstruction or resection / Unexpected medical conditions interrupting or changing the planned procedure) • Conversion (yes/no) • Reasons for conversion (bleeding / organ damage / adhesions or technical difficulties / anaesthesiologic contraindications) • Drain placement (yes/no) **Recovery-related:** • ICU (yes/no) • Clavien-Dindo (I/II/IIIa/IIIb/IVa/IVb/V) • Type of complications • Treatment of complications • Death (yes/no) • Time to first flatus (postoperative day) • Time to first mobilization (postoperative day) • Time to oral feeding (postoperative day) • Length of stay (days)

	• 90 days mortality • 90 days readmission **Cost analysis-related:** • Number of consultant surgeons (specifying whether ordinary or dedicated) • Number of non-consultant surgical assistants (specifying whether ordinary or dedicated) • Number of anaesthetic consultant (specifying whether ordinary or dedicated) • Number of non-consultant anaesthetic (specifying whether ordinary or dedicated) • Number of theatre nurse scrubber (specifying whether ordinary or dedicated) • Number of theatre nurse circulating (specifying whether ordinary or dedicated) • Portering staff (specifying whether ordinary or dedicated) • Amount of the following surgical instruments used: Maryland bipolar forceps, Fenestrated bipolar forceps, Permanent cautery hook, Cadiere forceps, Hot shears, Prograsp forceps, Vessel sealer, Harmonic Ace, staplers with reloads, sutures, drains, hemostatic consumables, diathermy consumables, scrub suits, dressings, drapes.
Follow-up	90 days
Statistical methods, Propensity Score Matching, Sample size	Data will be expressed as median and interquartile range (IQR) and number and relative percentage. Normal distribution of continuous variables will be assessed with the Kolmogorov-Smirnov test. Continuous variables will be analyzed using the student t-test or Mann-Whitney test and categorical variables using Fisher exact test or Chi-Square test as appropriate. Significant variables ($p<0.05$) at univariate and well-known variables affecting outcomes will be used to run the matching. All statistics will be 2-tailed and statistical significance will be accepted when $p<0.05$. All statistical analyses will be performed using IBM SPSS

	Statistics 27.
Duration of the Study	2023 - Ongoing
Ethical Committee	Comitato Etico Università Federico II -A.O.R.N. Cardarelli
Dataset and Datadictionary	Dataset and Datadictionary will be provided to all partecipant centres.
Data management	University of Naples "Federico II" will be responsible for collecting case report forms, controlling the quality of the reported data and generating reports and analyses, in cooperation with the Study Coordinator.
Insurance	NA
References	1. Jung M, Morel P, Buehler L, Buchs NC, Hagen ME. Robotic general surgery: current practice, evidence, and perspective. Langenbecks Arch Surg. 2015;400:283–92. https://doi.org/10.1007/s00423-015-1278-y. 2. Felder SI, Ramanathan R, Russo AE, Jimenez-Rodriguez RM, Hogg ME, Zureikat AH, et al. Robotic gastrointestinal surgery. Curr Probl Surg. 2018;55:198–246. https:// doi.org/10.1067/j.cpsurg.2018.07.001. 3. Liu R, Wakabayashi G, Palanivelu C, Tsung A, Yang K, Goh BKP, et al. International consensus statement on robotic surgery. Hepatobiliary Surg Nutr. 2019;8:345– 60. https://doi.org/10.21037/hbsn.2019.07.08. 4. de'Angelis N, Khan J, Marchegiani F, et al. Robotic surgery in emergency setting: 2021 WSES position paper. World J Emerg Surg. 2022;17(1):4. Published 2022 Jan 20. doi:10.1186s13017-022-00410-6. 5. Hinchey EJ, Schaal PG, Richards GK. Treatment of perforated diverticular disease of the colon. Adv Surg. 1978;12:85-109. 6. Okamoto K, Suzuki K, Takada T, et al. Tokyo Guidelines 2018: flowchart for the management of acute cholecystitis [published correction appears in J Hepatobiliary Pancreat Sci. 2019 Nov;26(11):534]. J Hepatobiliary Pancreat Sci. 2018;25(1):55-72.

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