EMC Emergency Managment Center
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Exploratory laparotomy following penetrating abdominal injuries: a cohort study from a referral hospital in Erbil, Kurdistan region in Iraq

Research protocol

1 November 2017

FINAL version

Karolinska Institutet

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Exploratory laparotomy following penetrating abdominal injuries: a cohort study from a referral hospital in Erbil, Kurdistan region in Iraq

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Protocol Details

Version 1.9
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Signatures of all Investigators Involved in the Study

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Summary

Study Rationale

The battle of Mosul was characterized by the use of improvised explosive devices, human shields and suicide bombers in an urban setting. It is unclear whether this type of warfare cause more extensive abdominal injuries to civilians than combatants. Understanding of the correlation between the severity of abdominal injuries, type of warfare and population affected is of importance when planning for surgical care in a conflict setting.

Aim

To assess whether civilians obtain more extensive abdominal injuries than combatants in an urban battle characterized by the use of indiscriminate weapons.

Study Design

An observational retrospective cohort study with longitudinal data collection.

All patients admitted with penetrating abdominal injury subjected to an exploratory laparotomy at Emergency Hospital, Erbil, between October 17, 2016 and July 16, 2017 will be included. Differences in demographics, injury mechanism, time since injury, clinical status on arrival, intraoperative findings, postoperative complications and outcome will be analysed.

Primary Objective

Differences in injury mechanism, organs injured, surgical treatment given, postoperative complications and outcome between civilians *and* combatants.

Secondary Objectives

Differences in surgical treatment given, postoperative complications and outcome between patients with prior surgical treatment of their injury *and* patients without prior surgical treatment.

Differences in surgical treatment given, postoperative complications and outcome between patients who receive surgical treatment less than 24 hours from injury *and* patients who receive surgical treatment more than 24 hours from injury will be analysed.

Statistical methods

Differences between groups will be analysed using t-test and regression models.

List of Abbreviations

EH	Emergency Hospital, Erbil, Iraq
Ex-lap	Exploratory laparotomy
ICRC	International Committee of the Red Cross
IED	Improvised Explosive Device
ISg	Islamic State Group
WHO	World Health Organization

List of Definitions

Civilians	Children <16 years, all women and men ≥50 years.
Combatants	Men 16-50 or combatants by own admission.
Exploratory laparotomy	Surgical incision through the abdominal wall into the abdominal cavity
PATI	Penetrating Abdominal Trauma Index Assess the severity of injury in patients with knife, gunshot or other penetrating wounds to the abdomen (appendix 1).
Penetrating abdominal injury	An injury penetrating the peritoneum into the abdominal cavity
Peritonitis	Rigid involuntary general tenderness of the abdominal wall.
Postoperative complication	Any deviation from the ideal postoperative course that is not inherent in the procedure and does not comprise a failure to cure. Classification of Surgical complications will be done according to Clavien-Dindo (appendix 2).
SSI	Surgical Site Infection is present when one of the following criteria are meet: i. Purulent discharge from surgical site ii. Positive culture iii. Surgical site requires reopening iv. SSI is present as judged by attending physician Severity according WHO guidelines (appendix 3).

Background

Trail location

In 2014, Islamic State Group (ISg) made significant territorial gains in several governorates in Iraq and captured key cities, including Fallujah and Mosul[1]. ISg is unique among terrorist groups in that it employs a combination of conventional maneuverer warfare with tactics such as human shields, improvised explosive devices (IED's), suicide bombers and drones in order to capture and hold territory. These tactics are indiscriminate, leading to excessive civilian casualties[2].

Emergency Hospital (EH) is one of two trauma hospitals in Erbil, a major metropolitan area in Kurdistan Region of Iraq. Erbil is located 94 kilometres east of the city of Mosul. Mosul is the provisional capital of the Nineveh region of Iraq. In mid-October 2016, the offensive to liberate Mosul from the ISg was initiated. EH was assigned by the Governate to exclusively provide care to injured from the armed conflict in and around Mosul. Since late December 2016 treatment facilities, run by other emergency care providers, have opened closer to Mosul. EH since then mainly served as a referral hospital.

The battle of Mosul formally ended on 10 July, 2017. The admission of causalities from Mosul to EH has since then diminished significantly. NGOs and other emergency care providers have also decreased their activities since.

Previous reports on exploratory laparotomy in conflict settings

Outcome of exploratory laparotomy (ex-lap) following war-related injuries has previously been extensively studied and reported on[3-7]. These reports have mainly concentrated on causes for and findings at ex-lap, and postoperative mortality (table 1). Few studies have focused on the differences in injury mechanism, complexity of injuries and outcome between civilians and combatants, especially in urban conflicts where IED's, human shields and suicide bombers are used[2].

Table 1. Findings at ex-lap and postoperative mortality in different conflicts

Conflict	Nb. of Ex-laps	Negative explorations	Small intestinal injuries	Colon injuries incl. rectum	Other injuries	Postoperative mortality
Chad,1980[3]	210	4,8%	33,0%	21,1%	32,7%	22,5%
Lebanon 1975-85[4]	1314	9,7%	24,7%	21,2%	55,0%	9,5%
Former Yugoslavia 1991-95[5]	93	4,3%	30,0%	28,4%	41,5%	10,8%
Gaza 2000-03[6]	230	6,5%	26,7%	17,9%	55,3%	7,4%
Mosul, Iraq, 2006[7]	153	15%	23,7%	18,7%	57,6%	33,3%

Justification

There is a need for better understanding of demographics and outcome of ex-lap following abdominal injuries sustained in urban conflicts where IEDs, human shields and suicide bombers are used. The use of these indiscriminate weapons could affect civilians to a greater extent than combatants[8]. We therefore hypothesis that the use of indiscriminate weapons in an urban setting causes more extensive abdominal injuries to the civilian population than to combatants. The knowledge gained from this study could be crucial when planning surgical staffing and facility needs in similar contexts.

Potential Risks and Benefits

Since this is an observational retrospective cohort study without any interventional methods it poses little to no harm for the participants. A potential benefit for future patients would be an increase understanding among health care providers regarding what kind of abdominal injuries indiscriminate weapons causes. Furthermore, a better understanding on what impact the use of indiscriminate weapons have on the civilian population.

Aim of Study

To assess whether civilians have more complex abdominal injuries than combatants in an urban battle characterized by the use of indiscriminate weapons.

Primary Measure

Differences in injury mechanism, organs injured, surgical treatment given, postoperative complications and outcome between civilians *and* combatants.

Secondary Measures

Comparison of surgical treatment given, postoperative complications and outcome between patients with prior surgical treatment of their injury *and* patients without prior surgical treatment.

Differences in surgical treatment given, postoperative complications and outcome between patients who receive surgical treatment less than 24 hours from injury *and* patients who receive surgical treatment more than 24 hours from injury will be analysed.

See chapter Data, *patient files*, for detailed primary and secondary measurements.

Investigation Plan

Study Design

A cohort study with retrospective longitudinal data collection using routinely collected clinical data.

Study Period

Consecutive patients presenting at EH between October 17, 2016 and July 16, 2017 that meet eligibility criteria will be included. Patient history information preceding hospital admission will be included.

Study Location

Emergency Hospital, Erbil, Kurdistan Region, Iraq.

Study Duration for Participants

Participants will be followed from admission until discharged from EH.

Study Population

Recruitment Methods

Patients will be included from the surgical ledger at the Surgical Department of EH.

Inclusion Criteria

- All patients treated with ex-lap due to conflict-related penetrating injury presenting at EH between October 17, 2016 and July 31, 2017 will be included.

Exclusion Criteria

- Patients who received treatment several times during the study period will only be counted as one patient.

Information for Patients and Consent

Since this study is based on data from routine care participants will not be informed, nor will consent be asked of participation, as this could introduce bias and confounding factors. There are moreover no risks or potential gains involved for participants. No incentives or inducements will be provided to any participant or staff involved.

Data

Data Sources

Data was routinely prospectively collected on paper based patient forms in the clinical setting at EH. A *patient database* with consecutive patients treated between October 17, 2016 and July 31, 2017 was created. It is expected that the database will contain a total of 1,800 patients to produce approximately 160 evaluable subjects. Paper based *patient files* will be queried for demographic information, combatant or civilian status, admission dates, discharge dates, whether the injury was conflict-related or not, geographical site for injury, cause and mechanism of injury, prehospital data, medical history, vital signs at hospital admission, anatomical data and details regarding extent of abdominal injury, number and type of surgeries, details on surgery, need for ICU care, in hospital complications, re-admission including cause of re-admission, outcome including death and cause of death. Paper based data will be entered into a computer database using Epidata entry software (The Epidata Association, Odense, Denmark).

Patient Files

- Time of admission (specified)
- Age in years (specified)
- Sex (Male/Female/Unknown)
- Ethnicity (Arabic/Kurdish/Other/Unknown)
- Civilian/Combatant (Iraqi/Peshmerga/ISg/Unknown/Other)
- Time of injury (specified)
- Geographical location where injury occurred (specified)
- War-related injury (Yes/No/Unknown)
- Cause of injury (Bullet/Shell/Mie/IED/Unknown/Other)
- Mechanism of injury (Gunshot/Stab/Blast/Crush/Fragment/Burn/Traffic accident/Unknown/Other)
- Care prior to admission to EH (First Aid/Medical/Surgery/None given/Unknown)
- Provider of care prior to EH (MSF/Aspen/ICRC/Samaritan Purse/DoH/None)
- Mode of transport to EH (Military/Private car/Motorcycle/Ambulance/Unknown)
- Medical history (Healthy/Prior surgery/ Prior medical/Unknown)
- Body temperature (specified in Celsius)
- Heart rate (specified in beats/min)
- Blood pressure (specified in systole/diastole mmHg)
- Pregnant (Yes/No/Unknown)
- Pregnancy status based on (Lab/Question/Status/Unknown)
- Site and extent of abdominal wound (specified)
- Other injuries (Yes/No/Unknown, specified)
- Preoperative haemoglobin (specified in g/dL)
- Preoperative transfusions (Yes/No/Unknown, specified)
- Use of preoperative radiology (Yes/No/Unknown, specified)
- Time and date of procedure (specified)
- Duration of procedure (specified in hours and minute)

- Antibiotics prophylaxis (Yes/No/Unknown, specified)
- Procedure done (appendix 1 for definition of findings)
- Perioperative complication (Yes/No/Unknown, specified)
- Postoperative antibiotic prophylaxis (Yes/No/Unknown, specified)
- Postoperative infection (Yes/No/Unknown, appendix 3 for definition)
- Other postoperative complication (Yes/No/Unknown, appendix 2 for definition)
- Need of postoperative intensive care (Yes/No/Unknown, specified)
- Postoperative transfusions (Yes/No/Unknown, specified)
- Use of postoperative radiology (Yes/No/Unknown, specified)
- Further surgery done (Yes/No/Unknown, specified)
- Discharge (Yes/No/Unknown, specified)
- Follow-up scheduled (Yes/No/Unknown, specified)
- Re-admission (Yes/No/Unknown, specified)
- Deceased during hospital stay (Yes/No/Unknown, specified)
- Remarks

Statistical Analyses

Sample Size

Due to the nature of the study, the sample size will be a convenience sample of the available cases during the study period. It is expected that approximately 160 subjects will be enrolled.

Statistical Methods

Analysis will be done by as treated. A 5% significance level will be used. The difference in dichotomous, such as postoperative complication (primary outcome), and categorical outcomes with more than two categories will be tested using chi-square or Fisher test. For differences in continuous variables t-test will be used. In order to adjust our analysis for possible confounders and effect modifiers we will then use linear, logistic, ordinal or multinomial regression models, according to the nature of the outcome (continuous, binary, ordinal or nominal) with injury mechanism as the dependent variable and civilian/combatant as the main explanatory variable. Important demographic and injury specific parameters such as geographical location, date, age, sex, and injured organs, will then be included in the model as potential confounders.

Safety and Monitoring

Participant Confidentiality

The use of identification numbers will ensure anonymity in the data analysis. The participant's age, gender and demographic characteristics will be used as identifying features for analysis. The research team will ensure the ethical principles of beneficence, non-maleficence, justice and respect of patients are adhered to throughout the study.

Data Collection and Management

All data will remain anonymous throughout the data entry and analysis process. Nominal data will not be distributed outside the study location, or appear in any report or publication. Participant names will only be known by the research team. Identification codes will be safeguarded at EH facilities for the duration of the study.

Ethical Considerations

Ethics

The study will be conducted according to ethical principles stated in the Declaration of Helsinki[9].

Ethical Review Board Approval

An approval from the Ethics Review Committee of the Directorate of Health, Department of Health, Erbil, Kurdistan Regional Governate will be obtained before initiating the study.

Conflict of Interest

This is an investigator-initiated study. No company has had any influence over study design. There are no known conflicts of interest with other parties.

Dissemination

Printed and electronic versions of the final report will be provided to all partners involved in this research. Main findings will be presented orally to hospital staff at EH. The research methodology and results will be presented at scientific conferences and published in peer-reviewed journals.

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Appendix 1: Penetrating Abdominal Trauma Index[10]

Overview

The Penetrating Abdominal Trauma Index (PATI) can be used to assess the severity of injury in patients with knife, gunshot or other penetrating wounds to the abdomen. The index can be used to compare performance of different emergency care settings.

Patient evaluation

1. 14 organs are examined
2. The risk associated with injury to each organ is graded from 1 to 5.
3. The estimated severity of each type of injury is graded from 1 to 5.

Organ Injured	Risk Factor	Injury	Injury Estimate
Duodenum	5	single wall	1
		≤ 25% wall	2
		>25% wall	3
		duodenal wall and blood supply	4
		pancreaticoduodenectomy	5
Pancreas	5	tangential	1
		through-and-through (duct intact)	2
		major debridement or distal duct injury	3
		proximal duct injury	4
		pancreaticoduodenectomy	5
Liver	4	nonbleeding peripheral	1
		bleeding, central or minor debridement	2
		major debridement or hepatic artery ligation	3
		lobectomy	4
		lobectomy with caval repair or extensive bilobar debridement	5
Large intestine	4	serosal	1
		single wall	2
		≤ 25% wall	3
		>25% wall	4
		colon wall and blood supply	5

Major vascular	4	≤ 25% wall	1
		>25% wall	2
		complete transection	3
		interposition grafting or bypass	4
		ligation	5
Spleen	3	nonbleeding	1
		cautery or haemostatic agent	2
		minor debridement or suturing	3
		partial resection	4
		splenectomy	5
Kidney	3	nonbleeding	1
		minor debridement or suturing	2
		major debridement	3
		pedicle or major calyceal	4
		nephrectomy	5
Extrahepatic biliary	2	contusion	1
		cholecystectomy	2
		≤ 25% common duct wall	3
		>25% common duct wall	4
		biliary enteric reconstruction	5
Small bowel	2	single wall	1
		through-and-through	2
		≤ 25% wall or 2-3 injuries	3
		>25% wall or 4-5 injuries	4
		wall and blood supply or >5 injuries	5
Stomach	2	single wall	1
		through-and-through	2
		minor debridement	3
		wedge resection	4
		>35% resection	5
Ureter	2	contusion	1

		laceration	2
		minor debridement	3
		segmental resection	4
		reconstruction	5
Bladder	1	single wall	1
		through-and-through	2
		debridement	3
		wedge resection	4
		reconstruction	5
Bone	1	periosteum	1
		cortex	2
		through-and-through	3
		intra-articular	4
		major bone loss	5
Minor vascular	1	nonbleeding small hematoma	1
		nonbleeding large hematoma	2
		suturing	3
		ligation of isolated vessels	4
		ligation of named vessels	5

where:

- The percent injury to an organ wall probably indicates the portion of the entire circumference involved.

organ score = (risk factor) × (injury estimate)

penetrating abdominal trauma index (PATI) = SUM (all injured organs)

Interpretation

- minimum PATI: 0
- maximum PATI: 200

Risk of postoperative complications

- The risk of postoperative complications is low if the PATI is ≤ 25.
- The rate of postoperative complications increases sharply if the PATI >25.

Appendix 2: Clavien-Dindo's Classification of Surgical Complications[11 12]

Grades	Definition
Grade I:	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions.
	Allowed therapeutic regimens are: drugs as antiemetic's, antipyretics, analgesic's, diuretics and electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside.
Grade II:	Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.
Grade III:	Requiring surgical, endoscopic or radiological intervention
Grade III-a:	intervention not under general anaesthesia
Grade III-b:	intervention under general anaesthesia
Grade IV:	Life-threatening complication (including CNS complications) ‡ requiring IC/ICU-management
Grade IV-a:	single organ dysfunction (including dialysis)
Grade IV-b:	multi organ dysfunction
Grade V:	Death of a patient
Suffix 'd':	If the patients suffers from a complication at the time of discharge, the suffix "d" (for 'disability') is added to the respective grade of complication. This label indicates the need for a follow-up to fully evaluate the complication.

‡ brain haemorrhage, ischemic stroke, subarachnoidal bleeding, but excluding transient ischemic attacks (TIA);
IC: Intermediate care; ICU: Intensive care unit.

Appendix 3: Surgical Site Infection defined by WHO[13]

- Superficial incisional, affecting the skin and subcutaneous tissue. These infections may be indicated by localized signs such as redness, pain, heat or swelling at the site of the incision or by the drainage of pus.
- Deep incisional, affecting the fascial and muscle layers. These infections may be indicated by the presence of pus or an abscess, fever with tenderness of the wound, or a separation of the edges of the incision exposing the deeper tissues.
- Organ or space infection, which involves any part of the anatomy other than the incision that is opened or manipulated during the surgical procedure, for example joint or peritoneum. These infections may be indicated by the drainage of pus or the formation of an abscess detected by histopathological or radiological examination or during re-operation. Organ infection is not included within the scope of this guideline.

Appendix 4: Case Report From

EMC Emergency Managment Center
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Exploratory laparotomy following penetrating abdominal injuries: a cohort study from a referral hospital in Erbil, Kurdistan region in Iraq

Case Report Form

1 November 2017

FINAL version

Karolinska Institutet

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Exploratory laparotomy following penetrating abdominal injuries: a cohort study from a referral hospital in Erbil, Kurdistan region in Iraq

Case Report From (CRF), version 171101, protocol: _____

Patient Data

Patient no ☐

1. Time of admission ☐ / ☐ / ☐ ☐ : ☐ ☐ Unknown

day month year hours minutes

2. Age ☐ in years ☐ Unknown

3. Sex ☐ Male ☐ Female ☐ Unknown

4. Ethnicity ☐ Arabic ☐ Kurdish ☐ Other ☐ Unknown

_____

If other, specify

5. Civilian/Combatant ☐ Civilian ☐ Combatant ☐ Unknown

If combatant ☐ Iraqi ☐ Peshmerga ☐ IS ☐ Unknown ☐ Other

_____

If other, specify

Investigators signature _____ / / _____

day month year

Validated by and date: _____

Exploratory laparotomy following penetrating abdominal injuries: a cohort study from a referral hospital in Erbil, Kurdistan region in Iraq

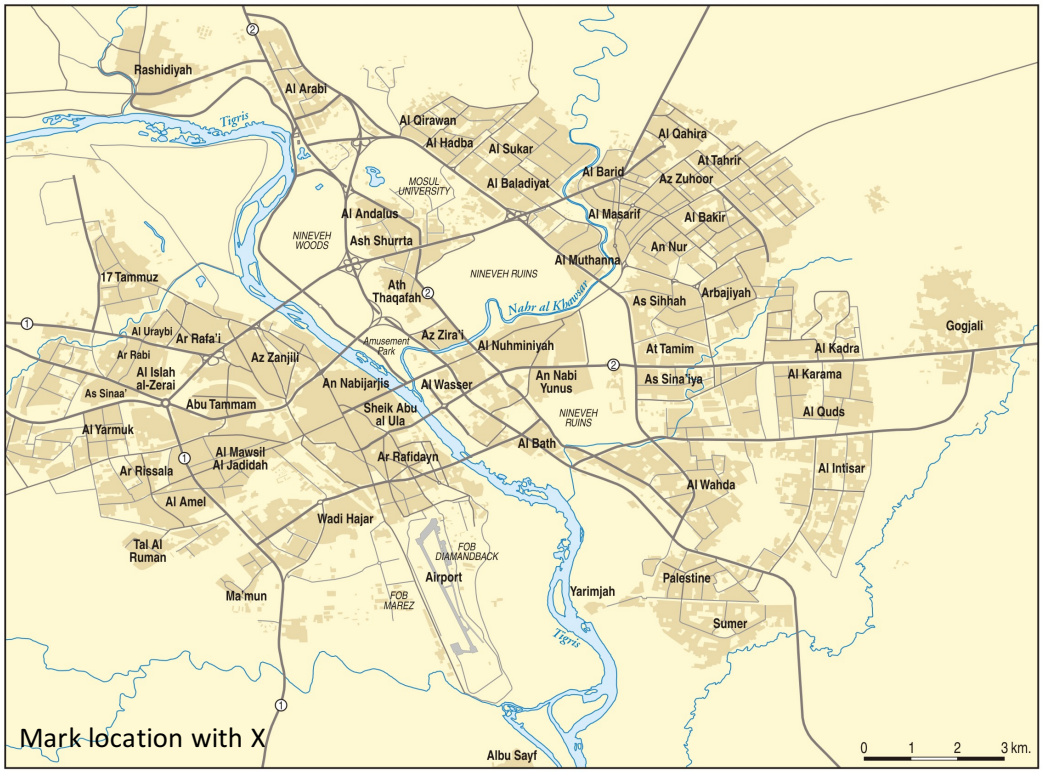
Case Report From (CRF), version 171101, protocol: _____

Injury Data

Patient no ☐

6. Time of injury ☐ : ☐ hours minutes ☐ / ☐ / ☐ day month year ☐ Unknown

7. Geographical location where injury occurred



☐ Unknown ☐ Other

If other, specify location where injury occurred

Investigators signature _____ / / day month year

Validated by and date: _____

Case Report From (CRF), version 171101, protocol: ______________________

Injury Data continued

Patient no [ ]

8. War-related injury

[ ] Yes [ ] No [ ] Unknown

9. Cause of injury
(If several causes number in same order as question 20 and 21)

[ ] Bullet [ ] Shell [ ] Mine

[ ] IED [ ] Unknown [ ] Other

If other, specify

____

10. Mechanism of injury
(If several number in same order as question 20 and 21)

[ ] Gunshot [ ] Stab [ ] Blast

[ ] Crush [ ] Fragment [ ] Unknown

[ ] Burn [ ] Other [ ] Traffic accident

If other, specify

____

Investigators signature ______________ / /

day month year

Validated by date: ______________________

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Case Report From (CRF), version 171101, protocol: _____

Prehospital Care Data

Patient no ☐

11. Care prior to admission to EH
(If several number in chronological order)

☐ First aid ☐ Medical ☐ None given

☐ Unknown ☐ Surgery

If surgery, specify procedure done

☐☐/☐☐/☐☐☐☐ of procedure
day month year

12. Provider of care prior to EH
(If several number in chronological order)

☐ MSF ☐ Aspen ☐ ICRC

☐ Unknown ☐ Samaritan Purse

☐ None ☐ Department of Health

Other, specify

Investigators signature _____ ☐☐/☐☐/☐☐☐☐
day month year

Validated by and date: _____

Case Report From (CRF), version 171101, protocol: _____

Prehospital Care Data cont.

Patient no ☐

13. Mode of transport to EH

(If several number in chronological order)

☐ Military ☐ Private car

☐ Motorcycle ☐ Ambulance ☐ Unknown

_____

Other, specify

14. Medical history

☐ Healthy ☐ Unknown ☐ Prior surgery ☐ Prior medical

_____

If prior surgery specify procedure(s)

_____

_____

_____

If prior medical condition(s) specify

_____

_____

Investigators signature _____ / / _____

day month year

Validated by and date: _____

Case Report From (CRF), version 171101, protocol: _____

Clinical Data at OPD

Patient no ☐

15. Body temperature ☐ in Celsius. ☐ Unknown

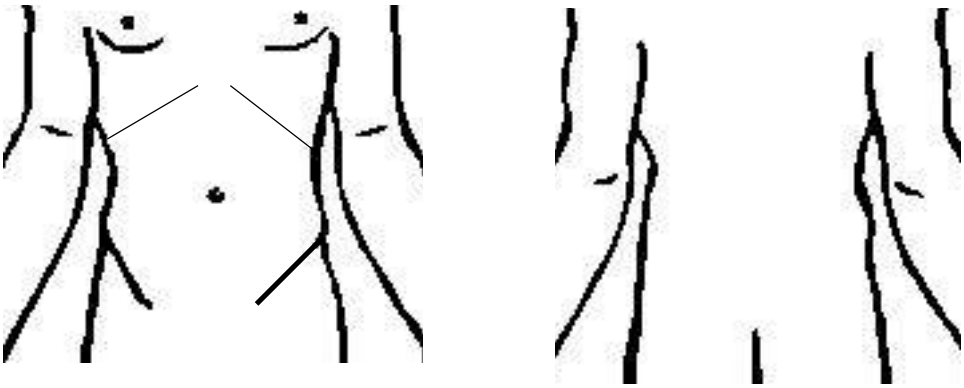
16. Heart rate ☐ in beats/min ☐ Unknown

17. Blood pressure ☐ / ☐ in mmHg ☐ Unknown
Systole Diastole

18. Pregnant ☐ Yes ☐ No ☐ Unknown

19. Pregnancy status based on ☐ Lab ☐ Question ☐ Status ☐ Unknown

20. Site and extent of abdominal wound



If >2 injuries use remarks

Mark each wound by number

1. _____
Brief description of size and depth

2. _____
Brief description of size and depth

Investigators signature _____ / / _____
day month year

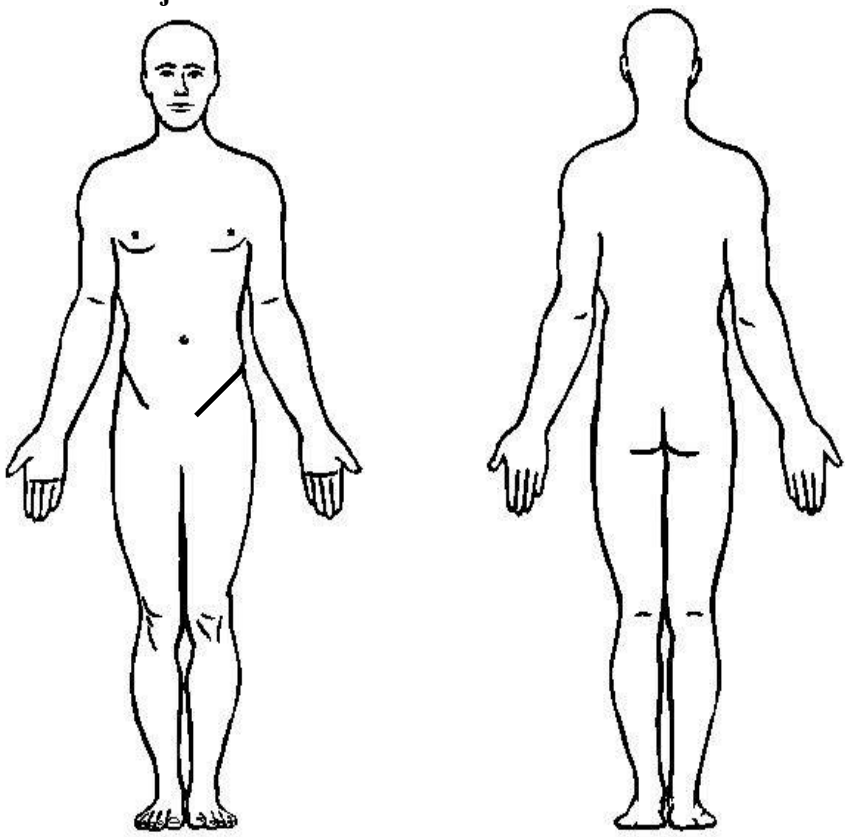
Validated by and date: _____

Case Report From (CRF), version 171101, protocol: _____

Clinical Data at OPD cont.

Patient no | |

21. Other injuries



If >3 injuries use remarks

Mark each wound by number

1. _____
Brief description of size and depth

2. _____
Brief description of size and depth

3. _____
Brief description of size and depth

Investigators signature _____ / / _____
day month year

Validated by and date: _____

Case Report From (CRF), version 171101, protocol: ___________________________

Preoperative Data

Patient no [ ]

22. Preoperative haemoglobin [ ] g/dL [ ] Unknown

23. Preoperative transfusions [ ] None given [ ] Unknown

[ ] Units of whole blood

[ ] Units of packed red blood cells

[ ] Units of Platelets

[ ] Units of Plasma

24. Use of preoperative radiology [ ] No [ ] Unknown

[ ] Computed Tomography (CT)

____

If CT was used, specify findings

[ ] Conventional radiology (X-ray)

____

If X-ray was used, specify findings

Investigators signature ______________________ / / ______

day month year

Validated by and date: ___________________________

Case Report From (CRF), version 171101, protocol: _____

Operative Data

Patient no ☐

25. Time and date of procedure ☐ : ☐ hours minutes ☐ / ☐ / ☐ day month year ☐ Unknown

26. Duration of procedure ☐ : ☐ hours minutes ☐ Unknown

27. Antibiotics prophylaxis ☐ No ☐ Yes ☐ Unknown

If yes, specify type, dose and duration

28. Procedure done ☐ If lack of space use remarks

(If several procedures are relevant. Mark most relevant with S.)

Primary haemostasis (damage control) ☐ Yes ☐ No ☐ Unknown

Removal of foreign bodies ☐ Yes ☐ No ☐ Unknown

Raphi of bowel ☐ Yes ☐ No ☐ Unknown

If raphi, specify site(s) and count(s)

Small intestinal resection with anastomosis ☐ Yes ☐ No ☐ Unknown

If anastomosis, specify site(s) and technique(s)

Investigators signature _____ / /

Validated by and date: _____

Case Report From (CRF), version 171101, protocol: _____

Operative Data cont.

Patient no ☐

Procedure done cont.

Colon resection with anastomosis ☐ Yes ☐ No ☐ Unknown

If anastomosis, specify site(s) and technique(s)

Stoma/Bowel deviation ☐ Yes ☐ No ☐ Unknown

If stoma(s), specify site(s) and technique(s)

Vascular repair ☐ Yes ☐ No ☐ Unknown

If vascular repair(s), specify location(s) and technique(s)

Splenectomy ☐ Yes ☐ No ☐ Unknown

Other ☐ Yes ☐ No ☐ Unknown

If other(s), specify location(s) and procedure(s)

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29. Perioperative complication ☐ Yes ☐ No ☐ Unknown

If yes, specify type

Investigators signature _____ / /

day month year

Validated by and date: _____

Case Report From (CRF), version 171101, protocol: _____

Postoperative Data

Patient no ☐

30. Postoperative antibiotic prophylaxis
(without treating a defined infection)

☐ No ☐ Unknown ☐ Yes

If yes, specify type, doses and duration

31. Postoperative infection
(If several is possible mark all with with appropriate postop. day.)

☐ No ☐ Unknown Appendix 3 for definition

Affecting the skin and subcutaneous tissue ☐ / / Date of diagnosis
day month year

Affecting the fascial and muscle layers ☐ / / Date of diagnosis

Affecting abdominal cavity ☐ / / Date of diagnosis

Sepsis ☐ / / Date of diagnosis

Measures taken (for ex. intensive care, iv antibiotics, dialysis)

Unspecified infection ☐ / / Date fo diagnosis

Explain and measures taken

Investigators signature _____ / /
day month year

Validated by and date: _____

Case Report From (CRF), version 171101, protocol: _____

Postoperative Data cont.

Patient no ☐

32. Other postoperative complication ☐ No ☐ Unknown Appendix 2 for definiton

Yes ☐☐/☐☐/☐☐☐☐ Date of diagnosis
day month year

Type and measures taken

33. Need of postoperative intensive care ☐ No ☐ Unknown ☐☐/☐☐/☐☐☐☐ Yes Date

---

If yes, specify reason(s) for intensive care

Discharged from Intensive Care Unit ☐☐/☐☐/☐☐☐☐ Date

34. Postoperative transfusions ☐ None given ☐ Unknown

☐☐ Units of whole blood

☐☐ Units of packed red blood cells

☐☐ Units of Platelets

☐☐ Units of Plasma

35. Use of postoperative radiology ☐ No ☐ Unknown ☐ CT ☐ X-ray

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If use of radiology, specify findings

Investigators signature _____ ☐☐/☐☐/☐☐☐☐
day month year

Validated by and date: _____

Case Report From (CRF), version 171101, protocol: _____

Postoperative Data cont.

Patient no ☐

36. Further surgery done ☐ ☐ ☐ / / Date

No Unknown 1.Yes

1. _____

If yes, specify procedure done

_____

_____

☐ / / Date

2.Yes

2. _____

If yes, specify procedure done

_____

_____

☐ / / Date

3.Yes

3. _____

If yes, specify procedure done

_____

_____

Investigators signature _____ / /

day month year

Validated by and date: _____

Case Report From (CRF), version 171101, protocol: _____

Postoperative Data cont.

Patient no ☐

37. Discharge ☐ No ☐ Unknown

Date of discharge ☐☐ / ☐☐ / ☐☐☐☐
day month year

Discharged Status

☐ Hospital care complete

☐ Left Against Medical Advice

☐ Unknown

☐ Transferred for further care

Transferred to where

Type of care planned

Investigators signature _____ ☐☐ / ☐☐ / ☐☐☐☐
day month year

Validated by and date: _____

Case Report From (CRF), version 171101, protocol: _____

Postoperative Data cont.

Patient no ☐

38. Follow-up scheduled ☐ No ☐ Yes ☐ Unknown

When and reason for follow-up

39. Re-admission ☐ No ☐ Yes ☐ Unknown

Date of re-admission ☐☐ / ☐☐ / ☐☐☐☐
day month year

Reason for re-admission

40. Deceased during hospital stay ☐ No ☐ Yes ☐ Unknown

Cause of death ☐ Unknown

Date of death ☐☐ / ☐☐ / ☐☐☐☐
day month year

Investigators signature _____ / / _____
day month year

Validated by and date: _____

Case Report From (CRF), version 171101, protocol: ___________________________

Postoperative Data cont.

Patient no

41. Remarks

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Investigators signature ______________________________ / / ________

day month year

Validated by and date: __________________________