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Randomized intraoperative peritoneal lavage for traumatic abdominal injuries

Submission date
15/09/2017

Recruitment status
No longer recruiting

Registration date
26/09/2017

Overall study status
Completed

Last Edited
25/11/2020

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims:
Abdominal washout at the end of a contaminated abdominal operation for trauma is a common sense intervention, but unsupported by evidence and potentially harmful. As some trauma patients present with ongoing peritonitis (inflammation of the stomach lining) from bowel injury, they are required control of the source of contamination, since bowel perforation (rupture) and soiling of the peritoneal cavity is associated with high morbidity (disease) and mortality (death). The use of irrigation for washout after the conclusion of an emergency abdominal procedure in a trauma patient is an ubiquitous, logical maneouver taught and practiced for many years, and considered to meet the standard of care; especially in the setting of abdominal contamination with enteral contents. There is, however, no quality evidence that supports it, and some data that may indicate is potentially deleterious. Factors that may potentially impact the desired effect include the volume of the effluent, were significant variability exist. Using large amount of Intra-abdominal irrigation (IAI) may dilute vs spread the contamination throughout the peritoneal cavity and lead to further complications. No specific recommendations are currently available to guide decision making in the operating room, and existing literature seems to suggest a dose-effect relationship with the desired outcome. Additional variables include the temperature of the effluent, and the source of contamination. The aim of this study to determine the optimal volume of abdominal irrigation that prevent surgical site infections (both deep and superficial), disruptions of the abdominal wall closure and fistula formations; and improve 30-day mortality.

Who can participate?
Individuals 14 years and older who sustained a traumatic injury and were brought to our trauma center during the study period.

What does the study involve?
After all abdominal injuries are repaired as is currently accepted and customary, participants are randomly allocated to one of three groups. Those in the first group are washed with 5 liters of sterile irrigation solution. Those in the second group receive 10 liters, and those in the third group receive 20 liters. The group distribution was made by chance. After all the appropriate data was collected and analyzed, we concluded that the best volume to irrigate patients after abdominal surgery for trauma is 5 liters.

What are the possible benefits and risks of participating?
There are no known immediate direct benefit to those taking part. But there should be benefits to future trauma victims now that the right amount of washing fluid is known. The actual risk of abdominal washing after surgery are temperature drops and increased chances of adherences after surgery. The actual number of times these potential effects may occur is still unknown.

Where is the study run from?
Advocate Christ Medical Center (USA)

When is the study starting and how long is it expected to run for?
April 2002 to July 2004

Who is funding the study?
Investigator initiated and funded (USA)

Who is the main contact?
Dr Eduardo Smith Singares MD FACS
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
AHC-IRB# 3252

Study information

Scientific Title
A randomized controlled trial on intrabdominal irrigation during emergency trauma laparotomy

Study objectives

The aim of this study to determine the optimal volume of abdominal irrigation that will prevent surgical site infections (both deep and superficial), disruptions of the abdominal wall closure and fistula formations; and improve 30-day mortality.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Advocate Health Care Institutional Review Board,12/28/2001, ref: AHC-IRB# 3252

Study design
A single center parallel clinical superiority randomized prospective study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Traumatic Abdominal injuries

Interventions
Once all operative repair is completed (including restoring intestinal continuity) and a decision to perform primary closure of the abdomen is made, the patients undergo random assignment to one of three treatment groups:

Group I:
Participants are assigned to receive 5L of irrigation with sterile, 37.8 C (100 F) 0.9% Sodium Chloride Irrigation USP (Baxter Healthcare Corp, Deerfield, IL) bottles. This volume is thought of as the "low volume", and is chosen based on existing practices within the trauma community in the City of Chicago and surrounding metropolitan area at the time of the trial as well the literature research performed during the study design phase, which may be found in the Reference list at the end of the published results. The designated volume is pulled one liter at the time from the OR Storage Console Warming Cabinet (Steris Corp. Mentor OH) and poured into the patient to avoid temperature loss. The washout is performed by the Attending Surgeon for the case and his assistant, in the usual sterile fashion. During irrigation all four quadrants of the abdomen were visualized and irrigated, using the mechanical action of the liquid to remove any residual, visible contamination and/or soiling, and finishing in the inframesocolic area were the small intestine loops were manually and gently rinsed. All remaining packs were removed during the exploration of each quadrant. Once irrigation is concluded the fascia is closed primarily and the skin is approximated if no colon injury is identified.

Group II:
Participants are assigned to receive 10L of irrigation with sterile, 37.8 C (100 F) 0.9% Sodium Chloride Irrigation USP (Baxter Healthcare Corp, Deerfield, IL) bottles. This volume is thought of as the "middle volume", and is chosen based on existing practices within the trauma community in the City of Chicago and surrounding metropolitan area at the time of the trial as well the literature research performed during the study design phase, which may be found in the Reference list at the end of the published results. The designated volume is pulled one liter at the time from the OR Storage Console Warming Cabinet (Steris Corp. Mentor OH) and poured

into the patient to avoid temperature loss. The washout is performed by the Attending Surgeon for the case and his assistant, in the usual sterile fashion. During irrigation all four quadrants of the abdomen were visualized and irrigated, using the mechanical action of the liquid to remove any residual, visible contamination and/or soiling, and finishing in the inframesocolic area were the small intestine loops were manually and gently rinsed. All remaining packs were removed during the exploration of each quadrant. Once irrigation is concluded the fascia is closed primarily and the skin is approximated if no colon injury is identified.

Group III:
Participants are assigned to receive 20L of irrigation with sterile, 37.8 C (100 F) 0.9% Sodium Chloride Irrigation USP (Baxter Healthcare Corp, Deerfield, IL) bottles. This volume is thought of as the "large volume", and is chosen based on existing practices within the trauma community in the City of Chicago and surrounding metropolitan area at the time of the trial as well the literature research performed during the study design phase, which may be found in the Reference list at the end of the published results. The designated volume is pulled one liter at the time from the OR Storage Console Warming Cabinet (Steris Corp. Mentor OH) and poured into the patient to avoid temperature loss. The washout is performed by the Attending Surgeon for the case and his assistant, in the usual sterile fashion. During irrigation all four quadrants of the abdomen were visualized and irrigated, using the mechanical action of the liquid to remove any residual, visible contamination and/or soiling, and finishing in the inframesocolic area were the small intestine loops were manually and gently rinsed. All remaining packs were removed during the exploration of each quadrant. Once irrigation is concluded the fascia is closed primarily and the skin is approximated if no colon injury is identified.

The randomisation is performed in a different room, where study personnel not assigned to clinical duties (and blinded to the patient’s identity and injuries) pull a pre-marked envelope with the group assignment on it, from an urn containing equal numbers of envelopes for the three arms of the trial, which is under the custody of one of the authors (SLS) at all other times. The surgical team is notified of the result of the randomization procedure in the operating room.

After the assigned intervention is completed patients were followed up during their inpatient stay and after discharge, for up to 30 days. Additional late follow up is provided in the Trauma clinic as needed or as indicated, according to the non-study interventions the patients received.

Intervention Type
Procedure/Surgery

Primary outcome(s)
30 day mortality is measured using the electronic medical record of the patient to retrieve the date of death, at the 30 day period or the day of death, whichever occurred first.

Key secondary outcome(s))
1. Intra-abdominal abscess is measured using the radiologic electronic medical record of the patient at the day of diagnosis or at 30 days, whichever occurred first
2. Wound infection is measured using the data about daily visual inspection of the wound and the criteria available in the methodology section of the protocol, using the electronic medical record of the patient at the day of diagnosis or at 30 days, whichever occurred first
3. Fistula formation is measured using the data about daily visual inspection of the wound and the criteria available in the methodology section of the protocol, using the electronic medical record of the patient at the day of diagnosis or at 30 days, whichever occurred first
4. Evisceration is measured using the data about daily visual inspection of the wound and the

criteria available in the methodology section of the protocol, and the resultant operative report, using the electronic medical record of the patient at the day of diagnosis or at 30 days, whichever occurred first

Completion date
01/11/2004

Eligibility

Key inclusion criteria
1. Patients aged 14 and above
2. Requiring an emergent exploratory laparotomy for trauma

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
204

Key exclusion criteria
1. Included the need for concomitant extra-abdominal surgery
2. The presence of a pelvic fracture and severe TBI (GCS <6 noted during the primary survey)
3. The use of the open abdomen technique
4. Intrabdominal vascular implants (but not primary repairs)
5. The presence of diaphragmatic injuries

Date of first enrolment
01/04/2002

Date of final enrolment
31/07/2004

Locations

Countries of recruitment
United States of America

Study participating centre

Advocate Christ Medical Center
4440 W 95th Street
Oak Lawn
United States of America
60453

Sponsor information

Organisation
University of Illinois at Chicago

ROR
https://ror.org/02mpq6x41

Organisation
Advocate Health Care

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
All patient level data, including the data sheets, randomization codes, and other relevant data, together with the additional documentation listed above, will be stored and made available upon request, with the Advocate Health Care Division of Research trial information repository. The date will be available after 1 year from the time of publication, and up to five (5) years. The participant's consent was obtained for this data. Information request from the depository may be directed to:

Christopher Blair
Director for Research and Innovation
Advocate Health Care
Website: https://www.advocatehealth.com/health-services/research-at-advocate/clinical-trials
email: christopherr.blair@advocatehealth.com

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2018	25/11/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes