Sterile conditions vs maximal hygiene conditions in laparoscopic cholecystectomy

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The aim is to address the following research question:Is there a higher incidence of postoperative (wound) infections when utilizing maximally hygienic measures instead of sterile measures in elective laparoscopic cholecystectomies?Secondary…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hepatobiliary therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON56941

Source
ToetsingOnline

Brief title
Maxhy-study

Condition

- Hepatobiliary therapeutic procedures

Synonym
cholecystolithiasis, gallstones

Research involving
Human

Sponsors and support

Primary sponsor: Deventer Ziekenhuis
Source(s) of monetary or material Support: intern gefinancieerd door het Deventer Ziekenhuis

Intervention

Keyword: Cholecystectomy, infection, Laparoscopic, Sterility

Outcome measures

Primary outcome

The primary endpoint of this study is the development of postoperative (wound) infection(s).

This will be assessed using the following measurement points:

- Each patient will undergo a regular physical checkup two weeks after the operation at the wound clinic, where a
wound score will be determined using the validated 'Southampton Wound Assessment Scale.'
- If a patient undergoes wound assessment earlier, the above method will be used for scoring.
- If a patient develops a wound infection later than the scheduled wound assessment but within 30 days, the above score will also be used.
- Other procedure-related infections, such as peritoneal infection, will be scored using the Clavien-Dindo classification.
- The surgeon will note whether there has been spillage of bile or gallstones for each patient.

The severity of the recorded wound infections will be assessed using the Southampton Wound Assessment Scale, a categorical method of recording the

severity of infection. This severity will also be related to patient factors, such as underlying comorbidities, with patient information collected from the electronic medical record.

Secondary outcome

- Saved costs: The saved costs of the maximal hygiene method compared to the sterile method, including the treatment of any complications, will be documented and analyzed. This will include saved material costs during surgery, costs of readmissions, costs of bacterial culturing and costs of treatment of surgical site infections. This will be from a hospital perspective.
- Sustainability: The reduction in waste material (in kg) in the maximal hygiene method compared to the sterile method will be documented and analyzed. The reduction in impact on the climate will be calculated in grams CO_2

Study description

Background summary

For decades, our focus has been on achieving the highest level of sterility to reduce the likelihood of infectious complications following surgical procedures. The foundations of this antiseptic approach can be traced back to the pioneering work of Joseph Lister (1827-1912) and the subsequent sterile practices established by Robert Koch (1843-1910), which were rooted in the extensive surgical techniques of the 19th and early 20th centuries. More than two centuries later, minimally invasive surgery has become the standard of care, with endoscopic techniques now being the norm for several thoracic and abdominal procedures. This transformation has substantially lowered postoperative complications and morbidity rates. Intriguingly, while these procedures are minimally invasive for patients, the equipment used has not necessarily become less complex; in some instances, it has even become more intricate. A significant portion of the equipment employed in modern surgery is disposable, primarily driven by cost considerations. This decision is often viewed as more economical when compared to the environmentally sustainable alternative of sterilization and reuse.

With pressure mounting in every hospital to address escalating healthcare costs while maintaining sustainability, it is only rational to scrutinize the equipment used during laparoscopic surgery. One of the most frequently performed laparoscopic surgeries in the Netherlands is the laparoscopic cholecystectomy. Annually, approximately 35,000 patients are diagnosed with gallstone disease in the Netherlands, leading to around 25,000 laparoscopic cholecystectomies each year (1,2). The risk of wound infections associated with this procedure is remarkably low, with an incidence rate of only approximately 2% (3,4). Consequently, the administration of preoperative antibiotics is considered unnecessary for uncomplicated cholecystectomies (2,4-6). Moreover, intra-abdominal infections that lead to peritonitis are also rare and typically sterile, with gallic peritonitides being the norm (7). In instances where infections do occur, they are often observed in patients with compromised immune systems (8).

There is already evidence suggesting that there is no increase in the rate of (wound) infections in a non-sterile setting during contaminated procedures, such as perianal procedures (9-12). The same can be said for minor excisions and the closure of traumatic wounds. Consequently, sterile conditions are no longer maintaned for these operations at this hospital. It appears that washing and sterilizing equipment previously used on patients is necessary, as there is evidence of this dating back to Lister and Koch in the 18th/19th century (13,14). Recalls have taken place due to inadequate sterilization of intraluminal instruments (15,16). However, in a recall of 1800 patients, not a single one appears to have been contaminated by an unsterilized endoscope (17).

Protective measures, such as surgical gowns, masks, and hairnets, seem to primarily function as a form of protection for healthcare personnel rather than providing direct benefits to the patient. Recent research conducted at Antoni van Leeuwenhoek Hospital has shown that the use of masks by non-sterile personnel does not lead to higher rates of wound infections. However, it does result in a 42% reduction in mask consumption.(18). In a prospective clinical study involving 200 patients undergoing hysterectomies, no differences were found between standard sterile conditions and reduced aseptic conditions. (19). This principle can be applied to laparoscopic cholecystectomies, as the removal of the gallbladder does not involve intra-abdominal sources of infection; bile and the gallbladder are essentially sterile. (20). The risk of infection from external sources is not expected to be higher than usual. If any microorganisms are introduced into the abdomen, the pathogenic microorganism load will be low enough for a patient's immune system, without immune suppression, to clear without difficulty. For instance, there is no evidence supporting the initiation of antibiotic prophylaxis for other traumatic penetrating injuries, such as gunshot wounds or non-organ-related knife wounds.

Proposal and Potential Impact

As mentioned previously, a significant number of laparoscopic cholecystectomies

are already being performed in the Netherlands, with yearly updates on indications for this procedure. Between 13 to 22 percent of the population in Western countries have gallstones (2). The size of the potential group undergoing laparoscopic cholecystectomy is significant, resulting in high levels of waste, CO2 emissions, and expenses. Therefore, limiting the use of sterile packs could have a considerable impact on decreasing waste, emissions, and expenses. A package containing frequently used items such as sterile gowns, overlays, and plastic bowls has been compiled for each of these procedures (see the Package Contents). This shipment includes excessive amounts of plastic and other packing materials. Some hospitals even provide individual wrappings for the aforementioned gowns, perpetuating the generation of waste. Therefore, using (previously sterilized) materials left over from other packages (and thus still maximally hygienic) could have a significant impact on operating room sustainability. For other minimally invasive, short-term elective laparoscopic surgeries (without the insertion of foreign body material), such as adnexal extirpations, uterine extirpations, or cystectomies, the same materials are used, making the potential impact even more significant.

With the research proposal presented here, we aim to explore the possibilities of working under maximally hygienic conditions instead of sterile conditions during laparoscopic cholecystectomies

Study objective

The aim is to address the following research question:
Is there a higher incidence of postoperative (wound) infections when utilizing maximally hygienic measures instead of sterile measures in elective laparoscopic cholecystectomies?

Secondary Objectives:

- What is the difference in severity of the documented postoperative (wound) infections between the two groups?
- Is the severity of the documented postoperative (wound) infections correlated with underlying comorbidities?
- What are the costs andsustainability of using maximally hygienic materials rather than sterile materials?

Study design

Randomized, double-blind, non-inferiority intervention study conducted at the Deventer Hospital, involving the inclusion of 332 patients over a period of 1.5-2 years.

Intervention

One group of patients will undergo surgery under normal (fully sterile) conditions, while the other group of patients will undergo surgery under maximally hygienic conditions.

Study burden and risks

This study does not differ significantly from standard care but involves more precise monitoring of the patient and their wounds. There is one brief outpatient visit once after the operation, lasting 5-15 minutes. This is a regular visit that alway takes place after this type of surgery.

Risks: Participation in this study does not impact the level of discomfort the patient experiences during or after the operation.
Benefits: This study contributes to a better understanding of sustainable practices, allowing future surgeries to meet the same standards.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients older than 18 years
- Patients that will undergo a planned laparoscopic cholecystectomy due to non-complicated gallstone disease

Exclusion criteria

- Patients undergoing an emergency surgery (48h).
- Patients with complicaties gallstone disease, such as cholecystitis, pancreatitis or cholangitis.
- Patients that have undergone an ERCP with papilotomy or stenting of the common bile duct.
- Patients that have had an invasive intervention or surgery within one week before the laparoscopic cholecystectomy.
- Patients that use medication that are immunosuppressive (e.g. methotrexate or monoclonal antibodies).
- Patients that have an active form of disease that need treatment with chemotherapy, immunotherapy or radiotherapy.
- Patients that chronically use antibiotics

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-11-2024
Enrollment:	332
Type:	Actual

Medical products/devices used

Generic name:	Medical Drapes;Medical Gowns and Medical Equipment Covers
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	07-08-2024
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL86344.100.24