



Special article

Surgical Protocol for Confirmed or Suspected Cases of Ebola and Other Highly Transmissible Diseases[☆]

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Outbreaks of viral haemorrhagic fevers such as Ebola can lead to imported cases in Europe and America. The eventuality of surgery in the setting of Ebola Virus Disease (EVD) is low, but the Spanish Association of Surgeons elaborated a surgical protocol for EVD.

Indication: Elective surgical procedures are not indicated. Emergency cases can be considered in: persons under investigation, possible cases and early confirmed cases. In some conditions usually treated by surgery a medical treatment can be tested.

Hospitals and Teams: All cases must be treated in high technology hospitals. These hospitals must be equipped with adequate means for healthcare provider's protection. All members of the healthcare team should practice thorough simulation prior to caring for a possible Ebola patient.

Surgical Protocol: This protocol is based on international guidelines on use of Personal Protective Equipment, protocols of other scientific societies, and specific recommendations for the operating room environment.

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Protocolo de actuación quirúrgica en casos confirmados o sospechosos de enfermedad por Ébola y otras enfermedades víricas altamente transmisibles

R E S U M E N

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Fiebre de Lassa
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Las epidemias por virus altamente transmisibles como la enfermedad por virus del Ébola (EVE) pueden generar casos importados a Europa y América. Aunque la probabilidad de actuación quirúrgica en ellas es baja, la Asociación Española de Cirujanos ha elaborado un protocolo de actuación quirúrgica.

Indicación: No está indicada la cirugía electiva. Puede necesitarse cirugía urgente en: personas en observación, casos probables y casos confirmados en fase precoz. En algunas condiciones de habitual tratamiento quirúrgico puede instaurarse una terapia médica conservadora con intención de evitar la intervención.

Hospitales y equipos: Los casos deben concentrarse en hospitales de alta especialización, únicos centros en los que se practique una eventual intervención quirúrgica. Estos deben garantizar la seguridad de los profesionales. Los equipos quirúrgicos han de recibir extensa formación mediante simulación.

Protocolo quirúrgico: Las recomendaciones se basan en protocolos de uso del equipo de protección individual, guías clínicas de otras sociedades y recomendaciones específicas para el área quirúrgica.

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Introduction

Since its initial description in 1976, there have been several outbreaks of Ebola Virus Disease (EVD) in western countries of the African continent. In 2014, cases were imported to Europe and North America. According to the World Health Organisation (WHO), all countries with international airports are at risk for experiencing imported cases. Therefore, they recommend a high level of medical vigilance, specific preparation of healthcare systems and preparation of detailed protocols for disease treatment.

The Spanish Association of Surgeons (*Asociación Española de Cirujanos*, or AEC) was required in 2014 by the Spanish Ministry of Health, Social Services and Equality to prepare a surgical action protocol for suspicious or confirmed patients with this disease. The AEC considers that the diffusion of this protocol may be of interest to hospitals and healthcare systems in our area of influence. This document expresses the position of the AEC regarding the surgical treatment of EVD, which can be adapted for other highly contagious diseases, such as Marburg virus, Lassa fever, Crimean-Congo haemorrhagic fever, etc.

There is very limited scientific evidence about aspects associating EVD and surgery. When this protocol was prepared, there were only 2 documents that specifically deal with this subject, both of which are from October 2014. The Surgical Infection Society published a generic declaration¹ and the American College of Surgeons presented a plan of action written by surgeons with surgical experience in developing countries.² This latter protocol has been adopted by several African countries. Our manuscript has been developed by the Surgical Infection Group of the AEC, based on the recommendation of both societies as well as the opinion of national and international experts in surgical infection. The protocol assumes that the general diagnostic aspects, transport of

samples, isolation of patients and protection of healthcare personnel have been communicated by the healthcare authorities and detailed in other documents, so this document only refers to surgical aspects.

Ethical Concerns

The fear of operating on EVD patients is reminiscent of the beginning of the human immunodeficiency virus (HIV) crisis. In a declaration statement published in 2004, the American College of Surgeons affirmed that, using the highest standards to control against infection, surgeons are ethically obliged to treat patients with HIV infection.³ In the opinion of the AEC, surgeons are obliged to provide care to each and every potential surgical patient, but the situation of surgical indication in patients with suspected EVD should be led by teams of volunteers who are specifically trained for this situation.

On the other hand, hospitals have the obligation to provide the necessary means in order to apply proper prevention measures for their staff in accordance with current regulations and clinical protocols. In the absence of said means, medical professionals cannot be required to provide treatment when the activity would carry a similar degree of risk as the pathology requiring surgery. Thus, the degree of medical care demanded should be proportional to the means available in cases that carry a high risk of infection or those with doubtful therapeutic benefits. Therefore, the option that would provide the greatest benefit while involving the least possible risk should be chosen.

Indication of Surgery in Patients With Suspected or Confirmed Ebola Virus Disease

We should differentiate between the indications for *elective* surgery and *urgent* surgery. We concur with the statement by the American College of Surgeons that *no elective surgery*

should be performed in cases of suspected or confirmed EVD. As for *urgent* procedures, it is unlikely that a patient with confirmed EVD would require surgery and, in addition, its general state at that moment would probably be a contra-indication. Therefore, an *urgent* procedure in the context of EVD would be more likely in patients who are suspected of having contracted the infection than in those with confirmed disease. It is possible that, in these probable cases or patients who are under observation, a pathology requiring surgical treatment may arise (for example, trauma, incarcerated hernia, acute abdomen), in which the indication for urgent surgery should be established. Likewise, one of the forms of presentation of the disease involves abdominal pain symptoms,¹ which could lead to the diagnosis of acute abdomen and a potential surgical intervention. Other conditions may also present that are usually considered in need of urgent surgery (appendicitis, cholecystitis, etc.) but may be able to be deferred or avoided with conservative medical treatment.

In short, urgent surgical procedures may need to be considered in patients in 3 different circumstances: persons under observation, probable cases, and confirmed cases in early phases of the disease. The decision to operate should be made individually based on the risks and benefits of the operation, while especially keeping in mind the risk of death according to the severity of the index disease, risk of death due to the pathology or the surgical procedure, risk for exposure of the surgical team and potential benefit of the urgent surgery proposed. The basic principle should be to offer the best treatment possible while minimising the risk of infection to other patients and hospital staff.

Operating Hospital and Team

Cases under observation and suspected or confirmed cases of EVD should be concentrated at a few highly-specialised hospitals, which should also be the only centres where any eventual surgeries would be performed. In a country the size of Spain, only 2 or 3 hospitals should probably be designated to treat these patients.

Patients suspected of having EVD who are haemodynamically stable and present a suspected pathology requiring urgent surgery should therefore be transferred as soon as possible to these reference hospitals for their diagnosis and potential surgical procedure. These hospitals should have the material means and appropriate facilities to guarantee the safety of the healthcare workers involved.

It is essential for the surgical teams designated to treat these patients to have extensive proper training. To this end, in hospitals that receive patients with suspected EVD, a few small surgical teams should be assigned, including surgical technologists, surgeons and anaesthesiologists capable of intervening in any type of urgent surgery. These teams should receive ample theoretical and practical training, including urgent situation simulation, use of protective gear and surgical technique protocol.

Nevertheless, cases may arise of patients suspected of having EVD, who are haemodynamically unstable and present with a pathology requiring urgent surgery, and cannot be transferred due to their clinical situation. For these cases, all

hospitals should be aware of the surgical action protocol, have adequate equipment and surgical teams trained in isolation measures, and assess the risks/benefits of the surgery according to the specific clinical situation. In general, it is not recommended to perform any type of procedure at hospitals that are not specialised due to the high risk for biosafety; therefore, every effort should be made to transfer the patient to a reference hospital.

Protocol for the Surgical Team

The Ebola virus is more easily transmissible than HIV,¹ so general recommendations that are applicable to HIV should be added to the specific recommendations published for Ebola referring to standard protection, contact and fluids.⁴⁻⁶

There are no guidelines about the personal protection of the medical staff in the operating room, so these recommendations are based on the protocols for the use of personal protective equipment (PPE), to which specific recommendations are added for the surgical area. Moving a patient to the operating theatre poses a risk to staff and other patients, so reference hospitals should consider creating specifically adapted pavilions with the necessary installations, isolated from the rest of the hospital, including operating rooms, changing rooms and showers. In the absence of these facilities, it is not unthinkable that a surgical procedure could be done in the isolation room of the patient, although the limited space could create an added risk for the hospital staff.

1. Surgical area

- a. Patients should be moved to the operating theatre in accordance with general guidelines for transporting EVD patients.
- b. Operating rooms are considered high-risk areas in the Doctors Without Borders (DWB) protocol,⁷ so all medical staff should be equipped with high-level PPE that completely cover the body, especially high-risk areas like the nostrils, mouth and eyes.
- c. Foot/shoe baths or a decontamination shower should be considered to provide prior disinfection before leaving the high-risk area, especially if there have been any spills of bodily fluids in the operating theatre. DWB recommends using a 0.5% chlorine solution (bleach). The decontamination shower is probably only possible in the case of appropriate facilities in specific pavilions. In contrast, the foot bath can be done upon leaving the operating room, using large containers.

2. Surgical check list

- a. The state of being a carrier or suspected carrier of EVD should be part of the pre- and postoperative discussion of the case and should be part of the safety check-list for surgery according to the WHO guidelines so that all medical staff present in the surgical area are aware of the potential risk of exposure.

3. Protective gear for medical staff in the surgical area

All personnel present in the operating room should be equipped with PPE that protect against contact and transmission by droplets.⁴ The following are recommended:

- a. Impermeable surgical gown classified as level 4 according to the Association for the Advancement of Medical Instrumentation (AAMI)⁸; Type 3B, 4B or 5B.¹¹
 - b. Complete cap/hood with long plastic visor that provides coverage below the neck; Type 3B, 4B or 5B.¹¹
 - c. Autonomous ventilation equipment is recommended with an integrated hood and gown system (AAMI level 4), such as the Flyte Steri-Shield[®] system⁹ or a TYCHEM-C[®] type of suit. In any case, the EN 14126 regulation should be complied with.
 - d. Fluid-resistant ultra-filter surgical mask; N95 masks should be considered if aerosols are generated, or FFP2 or FFP3 self-filtering masks.
 - e. Impermeable leg covers and impermeable shoes; Type 3B, 4B or 5b shoe covers.¹¹
 - f. Double surgical gloves; the outer gloves should be extra-long to protect the forearms, such as the Ansell X-Tenda Cuff[®] Extra-Long gloves (38.7 cm).¹⁰
 - g. Impermeable, closed, anti-fog surgical eyewear (EN 166, 167 and 168), such as Opface[®].
 - h. If the PPE is not sterile on the outside, a sterile surgical gown should be worn over it, which should be completely impermeable and long enough to reach the feet.
4. Sequence for donning the PPE, washing and surgical gown
- There are no published protocols that deal with this question. The sequence below is based on the opinions of the experts who have participated in the preparation of this protocol.
- 1) Hygienic washing of hands with an alcohol solution
 - 2) Sequential donning of the PPE in a large room outside the operating room, according to published guidelines. The protocol for suspected EVD cases by the Spanish Ministry of Health⁴ should be consulted, as well as the protocol by the University of Nebraska.¹¹ The 2 pairs of gloves should be surgical.
 - 3) External disinfection over the PPE of the forearms and gloves with a 70% alcohol solution; let air dry.
 - 4) Enter into the operating theatre.
 - 5) Don a sterile gown over the PPE.
 - 6) Don a pair of extra-long surgical gloves.
5. Surgical drapes and towels
- a. Drapes and towels for coverage around the surgical field should be AAMI level 4.
6. Technical aspects
- a. The choice of approach (open, laparoscopic, minimally invasive) should be made to minimise the risk of infection of the members of the surgical team. In American protocols, the endoscopic approach is considered the method of choice (thoracoscopy, laparoscopy), although it is necessary to consider the risk for particle and fluid aerosolisation and the difficulty for proper sterilisation of the material.
 - b. Sharp, cutting instruments should be avoided as much as possible. When required, they should be equipped with biosafety systems.
 - c. Fingers should not be used to grasp or reposition needles or scalpel blades. Tissue and sharp instruments should be handled with surgical instruments.
 - d. Verbal orders should be used to accompany the exchange of sharp or cutting instruments among the surgical team.
 - e. At the start of the intervention, a neutral area should be defined for sharp or cutting instruments in order to avoid passing these from hand to hand. To this end, a metallic tray or magnetic transfer drape are useful.
 - f. Sharp or cutting instruments should not be deposited on the Mayo instrument table, unless it is established as a neutral area.
 - g. The use of alternative cutting systems, such as the electrosurgical, should be maximised.
 - h. Preferably over the cold scalpel, the electrosurgical should even be used for skin incisions.
 - i. Mechanical sutures should be prioritised over manual sutures.
 - j. In endoscopic procedures, the thorax or abdomen should be decompressed before withdrawing the trocars to avoid spraying and diffusing materials from the cavities.
 - k. Under no circumstances should needle caps be put back on the needles.
 - l. The surgical team should have a container within reach for sharp or cutting instruments to dispose of them after their use.
 - m. The protective protocol against sharp or cutting instruments should be maintained to the end of the operation and during the disposal of surgical material.
7. Sequence for removing the PPE and surgical gown
- 1) If there has been any splashing of patient bodily fluids on the floor, decontamination should include a foot bath or full-body shower with bleach before leaving the high-risk area.
 - 2) The first pair of gloves should be removed in the operating room.
 - 3) The sterile surgical gown should be removed in the operating room.
 - 4) The PPE should be removed sequentially in a large room outside the operating theatre and in accordance with published guidelines.^{4,11}
 - 5) The surgical team should remove the gown, gloves and PPE with the mandatory aid of a trained observer who is also protected by a PPE, in an ample space next to the operating room.
 - 6) Extreme caution should be taken not to touch one's face, especially the nose, mouth, lips or eyes.
8. Treatment of surgical specimens and waste
- a. General guidelines published by healthcare entities should be followed.⁴⁻⁶ If there is no proper protocol for the treatment of samples that guarantees safety, the surgical specimens will not be processed.
9. Intraoperative accidents
- If an error in protocol occurs that involves the percutaneous or mucocutaneous exposure of a member of the surgical team to blood, secretions, bodily fluids or excretions of a patient with confirmed or suspected EVD, the affected member should:

- a. Immediately leave the procedure and wash the affected surfaces with soap and water.
- b. Irrigate mucous membranes (conjunctiva, for example) with copious amounts of water or conjunctival irrigation solutions.
- c. Immediately contact the Occupational Risk Prevention Department of the hospital.

Training

The members of the surgical team should be volunteers and receive theoretical and practical training, including simulation of donning and removing the PPE, as well as with specific surgical equipment.

Simulations should also be done of standardised surgical procedures before considering performing any actual procedure. It is necessary to create set teams of professionals who undergo permanent joint training during periods of epidemic outbreaks in order to achieve a rapport and understanding of the protocol.

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Conflict of Interests

The authors have no conflicts of interests.

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