THE VIRUCIDAL EFFICACY OF VARIOUS METHODS OF “LARYNGEAL MASK AIRWAY” DECONTAMINATION

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A laryngeal mask airway (LMA)

- Is a medical device that keeps a patient's airway open during anaesthesia or unconsciousness.
- It is inserted through the patient's mouth, down the windpipe, and once deployed forms an airtight seal on top of the glottis (unlike tracheal tubes which pass through the glottis).
- Allowing a secure airway to be managed by a health care provider.
Use of LMA

- They are most commonly used by anaesthetists to channel oxygen or anaesthesia gas to a patient's lungs during surgery and
- In the pre-hospital setting (for instance by paramedics and emergency medical technicians) for unconscious patients
LMA

- A laryngeal mask has an airway tube that connects to an elliptical mask with a cuff
- The cuff is inflated with a syringe of air
Reusable LMA

Disposable LMA
Decontamination problems with LMAs

- Concerns about device cleanliness and safety due to the significant amount of protein deposits found on LMAs after routine cleaning which included a chlorhexidine bath and steam sterilization.

- Although not consistent with national and international recommendations and also not with the Medical Device Regulation (EU) 2017/745, disposable LMAs are sometimes reused due to:
  - a shortage of LMAs or
  - a lack of knowledge

Microorganisms in saliva

- Oral secretions of the patient contaminate LMAs
- Thus, microorganisms that can be found in saliva can be transmitted between patients if LMAs are not decontaminated well
- This emphasizes the importance of the decontamination method used
Flora of saliva

- Streptococcus
- Prevotella
- Haemophilus
- Veillonella
- Fusobacterium
- Granulicatella
- Gemella
- Capnocytophaga

Zhou Yuhua. Acta Biochimica et Biophysica Sinica 42(10):2010
Hepatitis B, C and HIV

- HBV, HCV, and HIV are recovered in saliva

Human immunodeficiency virus (HIV)

- Only certain body fluids—blood, semen, pre-seminal fluid, rectal fluids, vaginal fluids, and breast milk—from a person who has HIV can transmit HIV.
- These fluids must come in contact with a mucous membrane or damaged tissue or be directly injected into the bloodstream (from a needle or syringe) for transmission to occur.
- In extremely rare cases, HIV has been transmitted by e.g. open-mouth kissing if both partners have sores or bleeding gums and blood from the HIV-positive partner gets into the bloodstream of the HIV-negative partner.
- HIV is not spread through saliva.
- Saliva of viremic individuals usually contains only noninfectious components of HIV indicating virus breakown.

2. Samuel Baron, et al. Why Is HIV Rarely Transmitted by Oral Secretions?
Conditions in which HIV can survive

If HIV were to survive outside of the body for more than a few minutes, it could only do so under these specific environmental conditions:

- Colder temperatures below 3.89 °C
- The ideal pH level for HIV is between 7.0 and 8.0, with the optimal pH of 7.1
- HIV can survive in dried blood at room temperature for up to six days, although the concentrations of virus in dried blood will invariably be low to negligible
- HIV survives longer when is not exposed to ultraviolet (UV) radiation. UV light quickly degrades viral DNA as well as the lipids that make up the virus' shell, rendering it incapable of attaching to and infecting other cells
Hepatitis C (HCV)

The hepatitis C virus is a blood borne virus. It is most commonly transmitted through:

- Injecting drug use through the sharing of injection equipment
- The reuse or inadequate sterilization of medical equipment, especially syringes and needles in healthcare settings
- The transfusion of unscreened blood and blood products
- HCV can also be transmitted sexually and can be passed from an infected mother to her baby; however these modes of transmission are much less common
- Hepatitis C is not spread through breast milk, food, water or by casual contact such as hugging, kissing and sharing food or drinks with an infected person

http://www.who.int/news-room/fact-sheets/detail/hepatitis-c
Conditions in which HCV can survive

According to the U.S. Centers for Disease Control and Prevention, HCV can survive on environmental surfaces at room temperature for at least 16 hours but no longer than four days.

- In almost all cases, hepatitis C is spread through contact with infected blood. Dried blood deposits may still carry the virus.
- Other bodily fluids, such as urine, sweat, or semen, do not carry a high enough level of the virus to pass on an infection. Regular contact or sharing a living space with someone who has the virus is not a risk.
Viral load in saliva from patients with chronic hepatitis C infection

- Hepatitis C virus can be detected in blood and other bodily fluids, such as saliva.
- The aim of this study was to detect and quantify the HCV-RNA in saliva and plasma from patients with chronic hepatitis C infections.
- Whole saliva and blood from 70 patients with chronic hepatitis C.
- The HCV-RNA load was performed by qRT-PCR.
- HCV-RNA was detected in 80% of patients in saliva and 92.85% in plasma.
- The median of the viral load in the plasma was of 4.87 log10, and in saliva, it was 3.32 log10, (p = 0.0005).
- HCV-RNA was detected and quantified in saliva samples, and according to the quantification levels, saliva may be a possible transmission source of HCV.

Santos X. J Infect Public Health. 2015
Hepatitis B

- Hepatitis B is usually spread when blood, semen, or other body fluids from a person with the Hepatitis B virus enter the body of someone who is not infected.
- The virus is very infectious and is transmitted easily through breaks in the skin or mucus membranes (nose, mouth, eyes and other soft tissues). This can happen through:
  - Sexual contact with an infected person
  - Direct contact with infected or contaminated blood, even in tiny amounts too small to see
  - Sharing personal items, such as toothbrushes, razors, syringes, or glucose monitors that have even microscopic amounts of blood on them
  - Direct contact with open sores of an infected person
  - An infected mother passing it to her baby at birth

https://www.cdc.gov/hepatitis/HBV/PDFs/HepBWhenSomeoneClose.pdf
Hepatitis B

Hepatitis B is also spread through saliva.
Hepatitis B is not spread through sneezing, coughing, hugging, or breastfeeding

- The hepatitis B virus can survive outside the body for at least 7 days. During this time, the virus can still cause infection if it enters the body of a person who is not protected by the vaccine.
- Although the virus can be found in saliva, it is not believed to be spread through kissing or sharing utensils.
- Studies also showed that HBV DNA can be found in saliva of patients with blood HBV DNA levels $\geq 10^6$ IU/mL.

http://www.who.int/news-room/fact-sheets/detail/hepatitis-b

Kidd-Ljunggren K, et al, J Hosp Inf, 2006 ; 64, 352-357
### Traumatic injuries due to LMA can cause bleeding

<table>
<thead>
<tr>
<th>Site of injury</th>
<th>Type(s) of injury</th>
<th>Mechanism(s) of injury</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharyngeal mucosa</td>
<td>Laceration</td>
<td>Forceful insertion, inadequate lubrication</td>
</tr>
<tr>
<td></td>
<td>Bruising</td>
<td>Prolonged insertion, too high cuff pressures</td>
</tr>
<tr>
<td>Laryngeal apparatus</td>
<td>Arytenoid dislocation</td>
<td>Direct trauma</td>
</tr>
<tr>
<td></td>
<td>Recurrent laryngeal nerve injury</td>
<td>Compression of the nerve in piriform fossa</td>
</tr>
<tr>
<td>Uvula</td>
<td>Trauma leading to ischemia and necrosis</td>
<td>Direct trauma</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Prolonged compression</td>
</tr>
<tr>
<td>Epiglottis</td>
<td>Bruising</td>
<td>Incorrect or forceful insertion, anatomical abnormalities</td>
</tr>
<tr>
<td></td>
<td>Laceration</td>
<td></td>
</tr>
<tr>
<td>Tongue</td>
<td>Frenular injury</td>
<td>Incorrect or forceful insertion</td>
</tr>
<tr>
<td></td>
<td>Lingual nerve injury</td>
<td>Compression of inferior or lateral surface of the tongue by cuff or tube of SGA</td>
</tr>
<tr>
<td>Teeth</td>
<td>Displacement</td>
<td>Direct trauma</td>
</tr>
<tr>
<td></td>
<td>Fracture of roots</td>
<td>Biting on SGA/bite block</td>
</tr>
<tr>
<td>Lips</td>
<td>Laceration</td>
<td>Direct trauma</td>
</tr>
<tr>
<td></td>
<td>Nerve injury</td>
<td>Compression by device, taping to device</td>
</tr>
</tbody>
</table>

An incidence of blood staining 20%

Michalek P. Biomed Res Int. 2015
The aim of this study was:

- To investigate the efficacy of different decontamination methods on LMAs which were contaminated with artificial saliva including HBV DNA
- It is also known that HBV has a higher resistance to decontamination compared to HCV and HIV
- To evaluate the possibility of reuse on basis of the DNA load and function control
Materials and methods

- Artificial saliva samples were inoculated with plasma of patients containing HBV DNA levels of $10^8$ IU/mL
- Disposable and reusable LMAs were inoculated by placing them in the inoculated saliva for one hour at 37°C
- Dried for 24 hours at room temperature
- After drying different decontamination methods were used
Decontamination methods

- Cleaning in a washer disinfector with a thermal disinfection phase of 1 min at 90°C ($A_0$ 600)
- Cleaning in a washer disinfector with a thermal disinfection phase of 5 min at 90°C ($A_0$ 3000)
- Cleaning in a washer disinfector with a disinfection phase of 1 min at 90°C followed by hydrogen peroxide gas plasma sterilization
- Cleaning in a washer disinfector with a thermal disinfection phase of 1 min at 90°C followed by ethylene oxide gas sterilization
- Cleaning in a washer disinfector with a thermal disinfection of 5 min at 90°C followed by steam sterilization at 134°C for 5 min (only for reusable LMAs)
- High level disinfection with peracetic acid 2% without cleaning
In each group at least 3 LMAs were used together with negative controls
Viral DNA isolation

- After decontamination, the LMAs were placed in a phosphate-buffered saline (PBS) solution for one hour at 37°C.
- In the PBS HBV DNA levels were determined by real time PCR (Qiasymphony Qiagen, Germany).
- The polyethylene glycol procedure was used for nucleic acid isolation from the artificial saliva samples and PBS solutions.
Function check of the LMAs

### HBV DNA levels measured in different decontamination methods

<table>
<thead>
<tr>
<th>Decontamination method</th>
<th>HBV DNA levels (log IU/mL) Re-usable LMA</th>
<th>HBV DNA levels (log IU/mL) Disposable LMA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>Control</td>
<td>Control</td>
</tr>
<tr>
<td>After decontamination</td>
<td>After decontamination</td>
<td>After decontamination</td>
</tr>
<tr>
<td><strong>Thermal disinfection (A₀ 600)</strong></td>
<td>2.50</td>
<td>2.50</td>
</tr>
<tr>
<td></td>
<td>1.49</td>
<td>1.49</td>
</tr>
<tr>
<td><strong>Thermal disinfection (A₀ 3000)</strong></td>
<td>2.59</td>
<td>2.94</td>
</tr>
<tr>
<td></td>
<td>1.49</td>
<td>1.79</td>
</tr>
<tr>
<td><strong>Thermal disinfection (A₀ 600) + Hydrogen peroxide gas plasma</strong></td>
<td>2.50</td>
<td>2.50</td>
</tr>
<tr>
<td></td>
<td>HBV DNA negative</td>
<td>HBV DNA negative</td>
</tr>
<tr>
<td><strong>Thermal disinfection (A₀ 600) + Ethylene oxide</strong></td>
<td>2.51</td>
<td>2.51</td>
</tr>
<tr>
<td></td>
<td>HBV DNA negative</td>
<td>HBV DNA negative</td>
</tr>
<tr>
<td><strong>Thermal disinfection (A₀ 3000) + steam ster.</strong></td>
<td>1.60</td>
<td>Not applied</td>
</tr>
<tr>
<td></td>
<td>HBV DNA negative</td>
<td>Not applied</td>
</tr>
<tr>
<td><strong>High level disinfection with 2% peracetic acid</strong></td>
<td>3.20</td>
<td>2.30</td>
</tr>
<tr>
<td></td>
<td>2.30</td>
<td>1.49</td>
</tr>
</tbody>
</table>
GH + MT promoter construct

GH gene
interons

pBR322

MT

G H gene with MT promoter cloned in pBR 322

cross breed transgenic and normal mice to study inheritance

transgenic mouse

transplantation

normal mouse

surrogate mother
Function check results

- The disposable LMAs were completely deformed after the thermal decontamination procedures.
- No deformation was observed in reusable LMAs.
Conclusions

- After disinfection – thermal as well as chemical – important levels of HBV DNA are found.
- After thermal disinfection with $A_0$ 600 followed by hydrogen peroxide gas plasma or ethylene oxide gas sterilization no HBV DNA could be detected on either disposable or reusable LMAs.
- But the disposable ones lost their function
Conclusions

- HBV DNA was not detected on reusable LMAs after steam sterilization.
- Reusable LMAs can be safely reused after cleaning, disinfection and sterilization.
- Single use LMAs can not be reused.
Conclusions

- The reuse of single use medical devices contains a danger for the patient
- It is the duty for the CSSD to protect the interests of the patients also in this regard!
Thank you