

THE PHARMACOECONOMIC VALUE OF THE ETHYLENE OXIDE STERILIZATION PROCESS IN THE HOSPITAL

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SUMMARY

Introduction / Objectives: Sterilization with Ethylene Oxide involves removing microorganisms from reusable and heat-sensitive medical devices. The aim of our study is to estimate the degree of use of ethylene oxide as a sterilizing agent by hospitals and to highlight the benefit-risk balance of this process. **Materials and methods:** The questionnaire survey, the economic evaluation of medical devices and the bibliographic investigation were tools that enabled us to carry out this work. **Results / Discussion:** Of a sample of ten questionnaires distributed to hospitals, only 20% were exploitable. The rest (80%) declared that they had other techniques of sterilization of

thermosensitive objects. The total price of the single-use medical devices selected was US \$ 132814.08 (US \$) while the price of sterilized medical devices for reuse was \$ 24645.6. The bibliographic survey clearly revealed the toxicity of ethylene oxide for humans and animals. **Conclusion:** According to the results of our study, the risks are numerous but manageable in favor of the economic benefits resulting from the sterilization of medical devices by ethylene oxide.

KEYWORDS: Sterilization, Ethylene Oxide, Safety, Risk, Cost.

I- INTRODUCTION

Sterilization of medical devices with Ethylene Oxide is one of the techniques widely used by hospitals including single-use and heat-sensitive medical devices. It is a toxic, carcinogenic,

flammable and explosive gas.^[1] For reasons of safety measures of personnels and products with regard to risks, it is noted that this process is disappearing in some developed countries. The aim of our study is to estimate the degree of use and the way in which Ethylene Oxide is used as a sterilizing agent at low temperature by hospitals and to highlight the benefit / risk balance of this process with economic evaluations.

II- MATERIALS AND METHODS

This was a four-month prospective analytical study (from 1 December 2015 to 27 March 2016). The questionnaire survey was carried out from December 2015 to March 2016 with the hospitals of the Kingdom. While the follow-up of sterilization procedures and economic evaluation of medical devices was carried out in January 2016 to the central sterilization service of the Mohamed V Military Training Hospital in Rabat. For this survey, we evaluated a sample of hospitals in the different cities of the Kingdom in order to have a general view of the use of Ethylene Oxide (Table 1) and to estimate the frequency of use of Ethylene Oxide in Morocco as a sterilizing agent in hospitals. The sample was 10 hospitals and participation was voluntary and the selection of hospitals was made by chance without specific criteria. Data were collected anonymously. For each questionnaire we assigned a unique identifier (anonymity) consisting of two letters and ten digits. The first letter was the name of the hospital city, the second letter was the name of the hospital, the first four digits indicated the date and month the hospital responded to the questionnaire, the year of the 2016 survey and the last digits indicated the questionnaire number.

Example: C M 1601 2016 03

We selected six medical devices (Figures 1-5) coming from three different operating units, taking into account the following criteria

- Does not support moist heat
- Does not support dry heat
- Susceptible to be sterilized with ethylene oxide
- Likely to be reused

For all this material, the follow-up was carried out from the pre-disinfection phase until the end of sterilization and storage in the clean room.

For the pharmacoeconomic study; we adopted the cost minimization methodology for costing. It is a method that shows the cheapest strategy.



Figure. 1: Electrosurgical scalpel. Figure. 2: Protective cover for microscope.

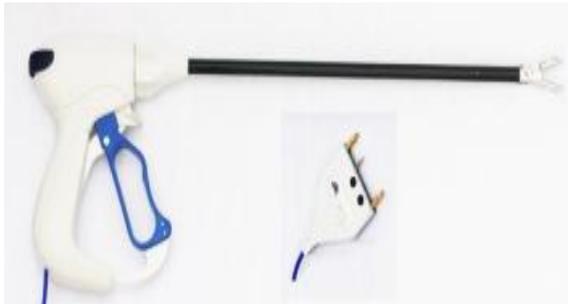


Figure. 3: Liga Sure for colostomy.



Figure 4: HARMONIC ACE® + laparoscopic Shears



Figure. 5: LigaSure Stapler Codivien.

The costs of a sterile medical device before use

Acquisition cost: This is a sum of expenses spent on the purchase of a medical device.

The cost of purchase = Purchase price + supply costs (the communication price, the storage price, etc.).

III. RESULTS

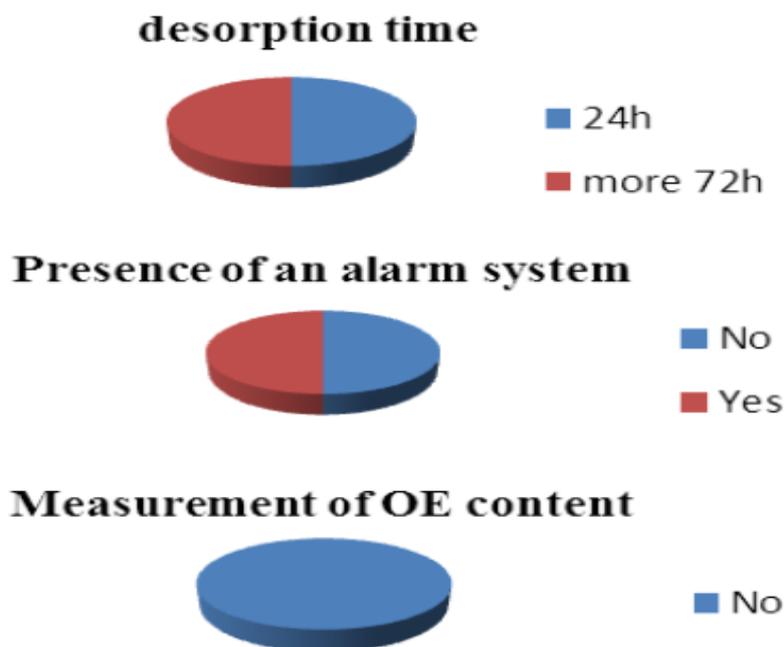
A. Results of the questionnaire survey on the use of the OE sterilizer.

Tableau. 1. Sécurité (utilisation, locaux, personnels, produits, environnement).

Parameters	% of hospitals
Loading / unloading system from OE sterilizer * Non automated system	100%
Number of staff handling in the sterilization chamber at the EO * more than 2 staff	100%
Presence of a zone of desorption *YES	100%
The desorption time 1) 24 hours 2) More than 72 hours	50% 50%
Handling area separated from other areas 1) yes 2) No	50% 50%
Presence of an alarm system 1) Yes 2) No	50% 50%
Presence of extinguisher * yes	100%
Presence of emergency exits *Yes	100%
Measurement of OE content *No	100%
Presence of protective equipment 1) Emergency Respirators: yes 100% 2) Track suits: yes 50% 3) Gloves: yes 50% 4) Goggles: yes	100% 50% 50% 100%

Table. 2. Training of personnel.

Parameters	% of hospitals with settings
Staff: Pharmacist Nurses Other (Caregiver)	50% 100% 100%
Staff are informed of the dangers of exposure to EO Yes	100%
Staff receive ongoing training Yes	10%



B. Results of the economic evaluation of medical devices: Case of MIHM V Rabat.

Table 3: Cost of Sterilization by EO

Cost of Sterilization by EO	
Cost of bio-cleaning	0,60 dhs
- Bio-cleaning product	
- Brush and swab	
- Pressurized air	
- Wet Wipe	
- Dry wipe (woven compress)	
Cost of packaging	2,50 dhs
- Double stained plastic paper 30 cm x 10 cm	
Cost of sterilization control	1,00 dhs
- Biological indicator	
- Physicochemical integrator	
- Printed sterile cycle recording paper disc	
- OE gas	
Amortization and maintenance amortization cost	2,75 dhs
Cost of manpower	0,185 dhs
Total Cost of a Sterile Unit / EO = 7,035 dhs	

Table. 4: Pharmacoeconomic Evaluation Results.

Medical Device	Unit Purchase Cost dhs	Sterilization Cost by EO dhs	Number of Use	Shortfall dhs
Electrosurgical Scalpel	60	7,037	10	530
Protective cover for microscope	80	7,037	3	219
LigaSure for colostomy	1100	7,037	3	3280
LigaSure Stapler Codivien	1200	7,037	3	3580
HARMONIC ACE® + laparoscopic Shears	2000	7,037	3	5980
Electrode cable for rhythmology	120	7,037	5	570
<u>Shortfall for the 6 items (dhs)</u>				14 160

Shortfall (dhs) = (Unit purchase cost - Sterilization cost per EO) x Number of use

Table 5: Annual Shortfall by the Ethylene Oxide Sterilization Process.

Shortfall	Value (dhs)
For 1 article	2360 dhs
For an average of 2 charges per week the MG per year	70 800 dhs
For an average of 2 charges per week the shortfall per year	6 796 800 dhs

IV - ANALYZES AND DISCUSSIONS

In the light of previous studies, some countries, such as France, have established regulations to protect health workers, patients and the environment, thus proposing the use of the ethylene oxide process, there would be no other means of sterilization. In 1997^[3], some countries, such as Germany, England and France offered alternative low-temperature sterilization processes such as plasma sterilization; peracetic acid; ozone; microwaves.^[2]

The total price of single-use medical devices selected in our study was 5,4 times than their counterparts sterilized for reuse. This is a study carried out for the first time in Morocco; it gives us a general idea of the practice of sterilization by Ethylene Oxide in hospitals. The sample to conduct the survey was difficult to reconstitute, since several questioned answered not having this process in their hospitals hence the difficulty of carrying out this study. During the economic evaluation of medical devices, we found a competition between companies because there was no reference price. Therefore, it was necessary to consider the price average proposed by the suppliers.

V- CONCLUSION

The process of sterilizing medical devices with ethylene oxide has a significant economic contribution.; But the risks are also numerous. We have identified many organizational failures to use this process in accordance with good Ethylene Oxide safe use practices in the hospitals surveyed. We have also shown the pharmacoeconomic interest of this process.

The implementation of a risk management strategy for toxic substances such as Ethylene Oxide, work safety measures will need to be steadily strengthened in order to achieve the economic benefits of sterilizing medical devices by Ethylene Oxide. The reprocessing of this medical equipment must be carried out under conditions guaranteeing the safety of the personnel and the patient.

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