Gastrointestinal endoscopes cleaned without detergent substance following an automated endoscope washer/disinfector dysfunction

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SUMMARY
Objective — To report cases of gastrointestinal endoscopies performed with endoscopes that were reprocessed without detergent substance during a period of dysfunction of the automated endoscope reprocessor (AER).
Method — A dysfunction of the AER for the cycles requiring detergent substance was reported at the Grenoble University Hospital on March 2005. During this period, 72 patients had potentially been exposed to a contaminated endoscope. A recall procedure was organized and serologic tests (HIV, HCV, HBV) were performed 3 and 6 months after the AER incident.
Results — Within the 72 patients convened, 56 (77.8%) were seen in consultation and accepted the serologic screening. Finally, serologic screening was done for 59 patients (81.9%) and no seroconversion for HIV, HCV, or HBV was observed. The final attrition rate was 13 patients (18.1%).
Conclusion — No viral infection was transmitted during the AER dysfunction. After this AER incident, the monitoring of the endoscopic procedures and the traceability of the cleaning process were both improved to prevent further incidents.

RÉSUMÉ
Objectif — Rapporter le cas de malades ayant eu un examen endoscopique réalisé à l’aide d’endoscopes nettoyés sans substance détergente durant une période de dysfonction d’un laveur-désinfecteur d’endoscopes (LDE).
Méthode — Une dysfunction d’un LDE pour les cycles qui requerraient le détergent a été rapportée au CHU de Grenoble en mars 2005. Durant cette période, 72 malades ont potentiellement été exposés à un endoscope contaminé. Une procédure de rappel des malades a été organisée, et des sérologies (VIH, VHB, VHC) ont été réalisées 3 et 6 mois après l’incident.
Résultats — Parmi les 72 malades convoqués, 56 (77,8 %) ont été vus en consultation et ont accepté le dépistage sérologique. Finalement, le dépistage a pu être réalisé pour 59 malades (81,9 %) et aucune séroconversion pour le VIH, VHB, ou VHC n’a été observée. Le taux d’attrition final était de 13 malades (18,1 %).
Conclusion — Aucune infection virale n’a été transmise durant la période de dysfonctionnement du LDE. À la suite de cet incident, la surveillance des examens endoscopiques et la traçabilité du processus de nettoyage ont été améliorées afin de prévenir des incidents ultérieurs.

Introduction
We report cases of gastrointestinal endoscopies performed with endoscopes that were reprocessed without detergent substance during a period of dysfunction of the automated endoscope reprocessor (AER).

Infection after gastrointestinal endoscopies occurs very rarely, although recent studies have reported such events [1-6]. Some of these infections were caused by a contaminated endoscope following inadequate cleaning or disinfection. This is of utmost importance for AER, which have become an essential part of most endoscopic units [7, 8]. Several studies have shown how infection transmission through endoscopies, in particular hepatitis C virus (HCV), could be limited by effective decontamination procedures [9-11]. Nevertheless, human or mechanical errors can occur. Management of a potentially contaminated patient by nosocomial agents is of great importance [12].

The purpose of this study was: 1) to analyze a series of 72 patients potentially exposed to an endoscope reprocessed without detergent substance; 2) to describe the crisis situation related to the risk of infectious disease transmission following the dysfunction of an AER in a gastrointestinal unit.

Method
Design
Data were collected within the University Hospital of Grenoble, in France, which is a 2200-bed Hospital.

Setting
The gastrointestinal endoscopy unit of the hospital, which performed 2 732 upper-gastrointestinal endoscopies and 1 137 lower-gastrointestinal endoscopies during the year 2004, has three AERs. A total of 27 endoscopes are available in the gastrointestinal endoscopy unit. Each endoscope undergoes microbiologic controls twice yearly.

The usual maintenance of the gastrointestinal endoscopes includes both manual and automated cleaning. After each gastrointestinal endoscopy, the endoscope is immediately immersed for 5 minutes in water containing detergent (Ampholyseine®) plus and channels are irrigated and brushed manually. Then the endoscope is washed in the AER (Adaptascope PAA, WD 440®).
ning is carried out with detergent, followed by rinsing and disinfection with per acetic acid. The AERs are checked every 1 000 cycles by the society Johnson & Johnson. A nurse from the gastrointestinal endoscopy unit reported an AER dysfunction on 30th March 2005. She was alarmed by the fact that a validation ticket was printed, while no detergent substance was available in the AER. After closer investigations made by the infection control department, it was confirmed that an AER was operating inadequately. The AER dysfunction was caused by a sensor that did not control the level of detergent substance any more, so as an undetermined number of detergent cycles were skipped. Consequently, some endoscopes had their cleaning cycles performed with water alone, whereas the disinfection cycles were respected. The period of dysfunction was established from 18th January 2005 to 30th March 2005, since the last maintenance control had been performed 17th January.

Patients

During the AER dysfunction period, 291 patients had one or more endoscopic examinations, for a total of 393 gastrointestinal endoscopies performed by the gastrointestinal endoscopy unit. The infection control unit reviewed and listed the patients whose gastrointestinal endoscopes were reprocessed by the dysfunctioning AER during the AER dysfunction period. According to national recommendations [13], risk factors for transmission of Creutzfeldt-Jacob disease were evaluated by patients’ clinical history before endoscopic examination. No risk factors were observed during the AER dysfunction period.

Interventions

The subsequent risk of transmission of exogenous infections to patients through gastrointestinal endoscopies reprocessed by this AER was analyzed by the medical staff of the gastrointestinal department in collaboration with the infection control unit. Since the first mandatory manual pretreatment with bactericidal detergent was respected, they concluded that bacterial contamination was very improbable. On contrary, since no test has yet been normalized the action of detergent substance against viruses, the risk of transmission of viral agents to patients could not be assessed. Finally, the maintenance of endoscopes reprocessed by this AER was declared to be inadequate according to national guidelines [14, 15].

The committee decided to recall the patients concerned, with all expenses associated with the AER incident paid by the hospital. The potentially contaminated patients were informed of the incident by letter, which was also sent to their general practitioner (GP). They were convened in the gastrointestinal unit and were seen by medical doctors from both the gastrointestinal and infection control departments. The consultation aimed to provide information orally on the AER dysfunction incident, to explain the subsequent risks of infection transmission and to offer serologic tests.

Main outcome measurements

Serologic tests for human immunodeficiency virus (HIV), hepatitis B virus (HBV), and HCV were done. The results were sent to the infection control unit, which informed the patients. The patients were given a prescription for a second HCV serology 6 months after the AER incident.

Results

Seventy-two patients were concerned by the recall procedure. The underlying pathologies for which gastrointestinal endoscopies were required were, in order of frequency: esophageal varices, neoplasm investigation, pancreatitis, inflammatory bowel disease, achalasia, digestive bleeding, lithiasis, sigmoiditis, iron deficiency anemia, diarrhea investigation, and nonspecific abdominal pain. The gastrointestinal endoscopies performed were the following: 31 colonoscopies, 4 duodenoscopies, 34 gastroscopies and 20 others (endoscopic ultrasound, ERCP).

Fifty-six patients out of 72 (77.8%) were seen in consultation and accepted the serologic screening. Among them, 18 (32.1%) presented an immunosuppressive pathology or were under immunosuppressive treatment. Within the 16 patients not seen in consultation, 3 did the serologic screening by themselves and transmitted the results to the infection control unit. The final attrition rate was 13 patients (18.1%) out of 72. Among them, 2 were already known to be positive carrier: one for HCV (viral RNA 660 000 UI HCV/mL), the other for HIV (viral load undetectable).

Serologic screening was done for 59 patients (81.9 %) and no seroconversion for HIV, HCV, or HBV was observed (Table I).

In addition, HCV serology was recontrolled 6 months after the AER incident and no seroconversion for HCV was observed among the 24 patients who agreed to recontrol it.

The positive results concerned patients who were already known to be positive carriers for HBV (N = 3) or HCV (N = 5) or who were vaccinated against HBV (N = 1). Eight subjects declared they were vaccinated against HBV, but only one presented a post-vaccine serology. This screening brought out six patients with HBV immunity.

Four gastrointestinal endoscopies were performed in patients known to have HCV infection. Endoscopes used for the HCV-infected patients were retrospectively traced. Patients whose endoscope was one of those traced were among those seen in consultation. No endoscopic biopsy was performed during these following endoscopies.

On the individual level, patients seen in consultation were very understanding. Most of them were very comprehensive and appreciated our desire for transparency. No legal complaint has been recorded to date.

Discussion

Few studies described the infectious risk management after AER dysfunction. However, according to the literature, inadequate maintenance of the endoscope is often cited as the hypothetical source of viral infection after endoscopy [4].

The absence of endoscopic transmission of HBV or HIV is consistent with most literature reports [3]. In contrast, nosocomial HCV transmissions have been described previously [2, 4, 11]. For this reason, among patients who were recalled, an initial HCV serology was done 3 months after the potential viral exposure, and a second serologic control was planned 3 months later. In reports of HCV transmission after endoscopies, endoscopic biopsies were isolated as an independent risk factor for HCV transmission.

Table I. – Serologic results for HIV, HBV, HCV (N = 59).

<table>
<thead>
<tr>
<th>Viral status</th>
<th>Before AER incident</th>
<th>3 months after AER incident</th>
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</thead>
<tbody>
<tr>
<td>HIV</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>HBV</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>HbsAg†</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>HCV protective antibodies</td>
<td>3‡</td>
<td>9‡</td>
</tr>
<tr>
<td>HCV</td>
<td>4³</td>
<td>4³</td>
</tr>
<tr>
<td>None</td>
<td>51</td>
<td>45</td>
</tr>
</tbody>
</table>

† Viral DNA negative.
‡ Including one patient with HBV post-vaccine protective antibodies.
§ Including three patients with viral RNA ranging between 125 000 and 660 000 UI HCV/mL.
infection [16]. In our series of patients, gastrointestinal endoscopies were performed with the same endoscope that had been used for the preceding case in a patient known to have HCV infection, but no endoscopic biopsies were done. Moreover, despite AER dysfunction for the detergent substance, disinfection of the endoscope had proceeded adequately. These two observations could explain the absence of HCV transmission among the survey patients.

To our knowledge, there have been no reported cases in the world literature of transmission of Creutzfeldt-Jacob disease by endoscopy. Recent data described lymphoid nodes, gingival tissue, lymphoid intestinal tissue, and blood as weakly infectious [17]. In France, procedures related to endoscopic medicine have been revised to take into account this emergent infectious risk. Nevertheless, from an ethical point of view, the risk of transmission of Creutzfeldt-Jacob disease by endoscopy has not been scientifically demonstrated, so that informing the patient has no ethical justification [13].

Look back investigations were mandatory after this AER incident. Since March 2001, the French regulation requires 2 washing steps and successive rinses before the endoscope disinfection, after the first mandatory manual pretreatment. For the moment, no testing protocol has validated endoscopes reprocessed without the two cleaning steps involving detergent substance before the endoscope disinfection. An adequate cleaning is the only way to limit the biofilm development that may be very fast between the patient examination and the endoscope disinfection. Short disinfection cycles (without detergent substance) at the beginning of the day have recently been validated for the AER Adaptascope PAA, WD 440®. In fact, the French regulation requires for each endoscope stocked longer than 12 hours a second disinfection before its utilization. Such short cleaning cycles have been validated by testing contaminated endoscopes after a standard cycle without detergent substance. These validated short cleaning cycles are of great interest, since they present the advantage of a double security. In fact, recall procedures represent important costs for the hospital and emotional stress for the patients. According to these considerations, in case of AER dysfunction with detergent substance only, recall procedures could be reevaluated.

To prevent future incidents the society Johnson & Johnson suggested a few modifications for the AERs of the gastrointestinal unit. A double control of the amount of solution circulating within the channels of any endoscope undergoing reprocessing will be performed. First, the sensor will still measure the amount of the detergent substance available, second, the flow of the solution running through the endoscope channels will be compared against preprogrammed values expected for the specific endoscope.

An audit of the maintenance procedures of 20 endoscopes was carried out in March 2005. No significant maintenance failure was observed. The endoscopes were partly controlled by microbiologic samples (N = 19) during the audit period. Forteen out of 19 samples (74%) were considered satisfactory, meaning that there were less than 10 CFU/100mL and no pathogen was observed. These results were consistent with the microbiologic controls previously realized in the endoscopic unit.

The utilization and maintenance of endoscopes are already standardized, so that we could enforce the present recall procedure and investigations. Nevertheless, nurses of the endoscopic unit were asked to systematically trace the replacement of detergent and disinfectant substance cans used for the AER. Moreover, security will be improved with the future acquisition of a software recording and analyzing the traceability data.

The final attrition rate of 18.1% found for the recalled patients was a potential bias. Nevertheless, another study with using a similar design and involving patients potentially contaminated after digestive endoscopies reported a similar dropout rate [12]. Since we sent an information letter to patients’ GP, it was possible that serologic screening was done and not transmitted to the infection control unit or that some patients did not want to realize the screening.

In conclusion, this incident highlights the importance of endoscope maintenance, in particular when AERs are needed to reprocess endoscopes. In our hospital, all the AERs have been carefully monitored since they were first put into use, so it was possible to trace every potentially contaminated patient. Nevertheless, after this AER incident, monitoring of the endoscope procedures and the traceability of the cleaning process were both improved to prevent further incidents.

Endoscopic maintenance procedures are required to guarantee a secure system when a dysfunction occurs at any step of the cleaning process. However, to maintain strict surveillance of endoscopes, decontamination procedures are the only solution to avoid transmission of nosocomial infections after gastrointestinal endoscopies, all the more when infected patients frequently undergo endoscopic examinations.

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REFERENCES


