

잘못된 소독제의 관리 및 기구 소독으로 인한 가성 유행발생

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한시현

유행발생이란?

- 전염병이 널리 퍼져 돌아다님(spread)
- 사회학적 측면] 특정한 행동양식이나 사상 따위가 일시적으로 많은 사람의 추종을 받아서 널리 퍼짐. 또는 그런 사회적 동조현상이나 경향(trend, fashion)
- Outbreak : The occurrence of **more cases of a disease or event than expected** during a specified period of time in a given area among a specific group of people

관련 용어 정의

- 토착화(Endemic) : 일상적으로 특정 의료관련감염의 발생률이 높은 것
- 대유행(Pandemic) : 감염병 유행의 범위(지역)가 넓은 것, **세계적 유행발생**
- 산발적, 간헐적(Sporadic) : Infrequent irregular cases
- 무리(Cluster) : 시간과 장소의 연관성이 있는 사례 발생 그룹
- **가성유행(pseudo-outbreak)** : 실제적인 감염이 아닌 어떤 것에 관련하여 사례가 증가된 것 : 진단이나 검사오류, 배양방법의 변화나 검사상 오염 등

유행조사의 목적

- 어느 의료기관이나 유행발생이 있을 수 있다.
- 감염유행이 더 이상 퍼지지 않도록 조치하고,
- 감염유행의 원인이 된 요인들을 확인하여,
- 유사한 유행이 다시 발생하지 않도록 적절한 중재방법을 개발하는 것
- 유행발생관리 경험 국내외 다른 의료기관에게 유사 감염유행발생을 예방하거나 감염유행 시 중재방법을 공유하는 것

의료관련감염(유행) 발생의 원인

- Endogenous patient flora
- Healthcare environments
- Medical equipment
- Healthcare personnel (HCP)
- Other patients
- Visitors

유행발생	보고연도	device	감염관리 또는 기술적 error
<i>Mycobacterium tuberculosis</i>	1989	Bronchoscope	Suction valve가 소독되지 않음
<i>P. aeruginosa</i> infection and colonization post-UGI endoscope	1991	UGI endoscope	자동소독기 결함
Bloody diarrhea associated with endoscopy	1992	Endoscope	내시경 소독 후 glutaraldehyde의 불충분한 행균
Proctitis following endorectal ultrasound examination	1993	Endoscope	내시경 소독 후 glutaraldehyde의 불충분한 행균
<i>P. aeruginosa</i> , Enterobacteriaceae bacteremia post-ERCP	1993	Endoscope	자동소독기 결함

유행발생	보고연도	device	감염관리 또는 기술적 error
Hepatitis C infection	1997	Colonoscope	부적절한 세척과 소독
Multidrug-resistant <i>Mycobacterium tuberculosis</i>	1997	Bronchoscope	불충분한 세척과 소독
Multidrug-resistant <i>P. aeruginosa</i> UTI and urosepsis	1997	Urodynamic transducer	Urodynamic test에 사용되는 transducer을 부적절히 재처리
Hepatitis B infection in a hospital and a nursing home	1997	Fingerstick blood sampling devices	혈액에 오염된 일회용 물품을 환자마다 교체하지 않음

Organism	년도	Product	Potential sources/Reservoirs
<i>B. cepacia</i> peritonitis and pseudobacteremia	1981 1992	Povidone iodine	1981-포비돈 아이오다인의 내재적 오염에 의한 의료관련감염 첫보고
<i>Burkholderia pickettii</i> bacteremia	1997	Saline solution	유치정맥카테터 관류용으로 사용한 saline
Pyodema in neonate	2000	Ultrasound coupling gel	초음파젤을 공용 용기로 사용하고 나무주걱으로 떠서 여러 신생아에게 재사용함

유행발생	보고연도	device	감염관리 또는 기술적 error
<i>P. aeruginosa</i> urinary tract infection following urodynamic studies	2001	방광압을 측정하기 위한 urodynamic system의 pressure transducer cover	Transducer cover는 일회용인데, 여러 환자에게 사용함
Increased incidence of catheter-related bloodstream infections	2006 2007	Positive pressure needleless valve used for intravascular access	Urodynamic test에 사용되는 transducer을 부적절히 재처리
<i>P. aeruginosa</i> infections after transurethral resection of the prostate(TURP)	2007	Steel biopsy needle guide	부적절한 재처리 과정; 높은 수준 소독 후 수돗물로 헹굼(제조사는 멸균수 권장)

FDA NEWS RELEASE

FDA is Investigating Reports of Infections Associated with Reprocessed Urological Endoscopes

Agency is taking action to remind health care providers about the proper way to clean certain devices for reuse

For Immediate Release:

April 01, 2021

“The FDA is investigating potential causes and contributing factors associated with reported infections and contamination issues from reprocessed urological endoscopes. We are very concerned about the three reported deaths—outside of the United States—associated with these infections, and we’re acting fast to communicate with health care providers and the public about what we know and what is still an emerging issue,” said Jeff Shuren, M.D., J.D., director of FDA’s Center for Devices and Radiological Health. **“While some reports indicate the potential causes could be inadequate reprocessing or device maintenance issues, we’re also evaluating other possibilities, including device design or the reprocessing instructions in the labeling. Although we believe that the risk of infection is low based on available data, we’re reminding health care providers how important it is to follow the labeling and reprocessing instructions to properly clean and reprocess the devices, including accessory components. We take all reports of adverse events seriously, and we encourage prompt reporting to the FDA to help us identify and better understand the risks associated with reprocessed medical devices.”**

- 2017년 1월 ~ 2021년2월20일 : 재처리와 관련된 가능한 오염문제 450개 보고 / 이중 3명 사망
- 현재 FDA 조치사항 : 2015년 십이지장 내시경 재처리 관련 감염 조치사항과 같이 배양 검사, 지침 업데이트 시행



Infections and outcomes after cardiac surgery—The impact of outbreaks traced to transesophageal echocardiography probes

- **Background:** Infections are a frequent complication of cardiac surgery. The intraoperative use of transesophageal echocardiography (TEE) may be an underrecognized risk factor for post-operative infections. The aim of this study was to investigate infection rates and outcomes **after cardiac surgery in a nationwide cohort**, especially in relation to periods where surface damaged TEE probes were used.
- **Methods:** This was a retrospective, observational study at Landspítali University Hospital. All consecutive cardiac surgery patients from **1 January 2013 to 31 December 2017** were included. Patients' **charts were reviewed** for evidence of infection, post-operative complications or death.
- **Results:** During the study period, **973 patients** underwent cardiac surgery at Landspítali and **198 (20.3%) developed a post-operative infection**. The most common infections were: Pneumonia (9.1%), **superficial surgical site (5.7%)**, bloodstream (2.8%) and **deep sternal wound (1.7%)**. Risk factors for developing an infection included: **The duration of procedure, age, insulin-dependent diabetes, EuroScore II, reoperation for bleeding and an operation in a period with a surface damaged TEE probe in use**.
- Twenty-two patients were infected with a multidrug resistant strain of *Klebsiella oxytoca*, 10 patients with *Pseudomonas aeruginosa* and two patients developed endocarditis **with *Enterococcus faecalis***. All three pathogens were cultured from the **TEE probe** in use at respective time, after decontamination. The 30-day mortality rate in the patient cohort was 3.2%.
- **Conclusions:** The intraoperative use of surface damaged TEE probes caused two serious infection outbreaks in patients after cardiac surgery. **TEE probes need careful visual inspection during decontamination and probe sheaths are recommended**.

TABLE 3 Presented in the table are factors associated with the development of post-operative infection in a cohort of 973 cardiac surgery patients

Risk factors for developing a post-operative infection—a univariate analysis				
Variable	Infected (n = 198)	No infection (n = 775)	Unadj. OR (95% CI)	P-value
Duration of procedure	279 min (SD 121.1)	233 min (SD 78.7)	1.005 (1.003-1.006)	<0.001
Age (y)	69.8 (SD 10.48)	65.9 (SD 11.62)	1.034 (1.018-1.050)	<0.001
Extracardiac arteriopathy ^a	18 (9.1%)	40 (5.2%)	1.837 (1.029-3.281)	0.040
Critical pre-op condition ^a	20 (10.1%)	28 (3.6%)	2.998 (1.651-5.444)	<0.001
Insulin-dep. diabetes mellitus	20 (10.1%)	31 (4.0%)	2.697 (1.502-4.843)	0.001
NYHA class				
0	17 (8.6%)	77 (9.9%)	Reference	
I	13 (6.6%)	84 (10.8%)	0.701 (0.320-1.538)	0.375
II	50 (25.3%)	307 (39.6%)	0.738 (0.403-1.350)	0.324
III	57 (28.8%)	181 (23.5%)	1.426 (0.780-2.609)	0.249
IV	61 (30.8%)	126 (16.3%)	2.193 (1.194-4.027)	0.011
Angina at rest	37 (18.7%)	97 (12.5%)	1.606 (1.060-2.435)	0.026
Ejection fraction	50.1% (SD 12.20)	54.1% (SD 10.49)	0.970 (0.956-0.984)	<0.001
Pulm. art. pressure ^b	42 mm Hg (SD 12.7)	38 mm Hg (SD 13.4)	1.024 (1.005-1.043)	0.015
Recent MI ^a	48 (24.2%)	130 (16.8%)	1.588 (1.090-2.312)	0.016
Urgency of procedure ^a				
Elective	94 (47.4%)	417 (53.8%)	Reference	
Urgent	76 (38.4%)	310 (40.0%)	1.088 (0.777-1.522)	0.625
Emergency	26 (13.1%)	42 (5.4%)	2.746 (1.604-4.702)	<0.001
Salvage	2 (1.0%)	6 (0.8%)	1.479 (0.294-7.441)	0.635
Euroscore II	2.9 (IQR 1.62-8.70)	1.6 (IQR 1.00-3.10)	1.096 (1.066-1.127)	<0.001
Reoperation for bleeding	21 (10.6%)	43 (5.5%)	2.020 (1.169-3.490)	0.012
Contaminated TEE period ^c	79 (40.1%)	249 (32.1%)	1.402 (1.016-1.935)	0.040

^aSee definitions under Table 1.

^bThe pulmonary arterial pressure was excluded from the multivariate analysis due to a large number of missing values.

^cOperation in a time period where a damaged and contaminated TEE probe was in use.

Statistically significant values in bold ($P < 0.05$)



FIGURE 1 The tip of one of the transesophageal echocardiography probes in use during the study period. With magnification and specific lighting used in this photograph, numerous superficial scratches and a crack (arrow) in the plastic casing can be visualized. The damage was not obvious to the naked eye. The outbreak strains of *Pseudomonas aeruginosa* and *Enterococcus faecalis* were isolated from this crack, after the probe had been decontaminated and was ready for use (Photo: Thorkell Thorkelsson) [Colour figure can be viewed at wileyonlinelibrary.com]

III. 소독과 멸균의 실제⁶

의료관련감염 표준예방지침

1 세척



세척은 적절한 소독이나 멸균을 위한 필수요건으로 의료기관에서는 세척에 대한 규정을 수립하고 규정에 따라 실시하며 이를 모니터링한다.

(3) 세척을 위해 분해가 필요한 기구는 제조사의 권고에 따라 분해한다.

(4) 세척과정에서 기구 표면의 손상이나 부식 등을 확인하여 이상이 발견된 경우에는 세척 후 기구관리부서로 의뢰한다.

(5) 세척도구(솔, 스펀지 등)는 재사용 시 사용대상의 수준에 적합한 재처리과정을 거친다(세척한 후 건조하거나 소독 또는 멸균).

(6) 세척제는 기구의 재질과 오염물질의 성분, 형태 등을 고려하여 오염 제거에 효과적이며 행균이 용이한 것으로 사용한다.

(7) 세척제가 남아 있으면 소독 및 멸균과정을 방해할 수 있으므로 충분히 행균다.

Glutaraldehyde 소독액에 의한 대장염의 발생

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채현석 · 김성수 · 이강문 · 김병욱 · 한석원 · 이창돈
최규용 · 정인식 · 선희식 · 안창혁* · 이은정†

- 목적: Glutaraldehyde를 포함한 내시경 소독제는 장 점막과 접촉 시 장 점막에 손상을 일으킨다. Glutaraldehyde에 의한 대장염은 대개 대장내시경이나 S장내시경검사 시에 소독액과의 부주의한 접촉에 의해 생기는데 저자 등은 뜻하지 않은 glutaraldehyde에 의한 대장염을 경험하였기에 그 증상 및 임상적 과정에 대해 기술하고자 한다.
- 대상 및 방법: 대장내시경은 통상적인 방법으로 시행하였으며, 하부 장관의 증상이 있었던 5명의 외래 환자에서 polyethylene glycol (2,000~3,000 mL)로 장을 세척한 후 대장내시경 검사를 하였다. 다른 2명의 환자는 S장내시경검사를 같은 날 시행하였다. 이들 모든 환자는 대장내시경검사 시행 후 24시간내에 혈성 설사, 구토, 산통의 복부 통증을 주소로 응급실에 내원하였다. 이들 중 S장내시경검사를 한 환자에서 응급 내시경을 다시 시행하였다.
- 결과: 내시경 소견은 내시경과 접촉이 있었던 부위에서만 미만성의 부종, 발적이 있었고 얇은 궤양을 보였다. 그러나 접촉하지 않은 원위부의 대장 점막은 거의 정상 소견이었으며 이 두 부위의 경계는 명확히 구분할 수 있었다. 현미경학적 소견으로는 장 점막은 부종, 급성 다핵백혈구의 침착과 섬유농성의 삼출물이 있었다. 검사실 소견은 말초 혈액에서 백혈구 증가 이외에는 비특이적 소견이었으며 혈액과 대변의 세균배양 검사는 음성이었다. 대장염의 증상은 대개 일주일 내에 없어졌으며 평균입원기간은 9일이었고 합병증 없이 회복되어 퇴원하였다.
- 결론: Glutaraldehyde 대장염은 내시경 후 갑자기 급성 출혈성 장염이 집단적으로 생기는 경우 의심하여야 하며 이에 대한 증상 및 예후를 예측하고 있을 필요가 있다.

III. 소독과 멸균의 실제⁶

4 기구에 따른 재처리 방법

연성 내시경(flexible endoscope)

(4) (소독) 높은 수준의 소독제에 침적하여 내시경의 내강을 포함한 모든 면에 소독제가 완전히 접촉할 수 있도록 한다. 재사용 소독제는 유효 농도가 적정하게 유지되는지 여부를 확인한다(부록, 「표 3.4.1. 내시경에 사용할 수 있는 높은 수준 소독제」). 만일 소독 단계에서 자동세척 소독기를 사용하는 경우에는 (3)까지의 과정을 거친 후 제조사의 지침에 따라 기기의 특성과 사용 방법을 확인하여 소독을 시행한다.

(5) (헹굼) 내시경은 모든 채널 내부를 주사기를 사용하여 물로 충분히 헹군다.

(6) (건조) 70~90% 알코올로 모든 채널을 통과시킨 후(제조사의 금기사항이 아니라면), 압축공기를 사용하여 건조한다.

Investigation and control of an outbreak of urinary tract infections caused by *Burkholderia cepacia*-contaminated anesthetic gel

Mingmei Du^{1†}, Linjian Song^{2†}, Yan Wang^{3†}, Jijiang Suo¹, Yanling Bai¹, Yubin Xing¹, Lijun Xie¹, Bowei Liu¹, Lu Li¹, Yanping Luo^{2*} and Yunxi Liu^{1*}

- Background: This report describes an outbreak of 71 patients developed *B. cepacia* urinary tract infection (UTI) by contaminated single-use anesthetic gel.
- Methods: Epidemiological investigation of patients with *B. cepacia*-positive urine or blood samples between March 19, 2018 and November 15, 2018 was conducted to identify the source of infection. Microbiological samples from hospital surfaces, endoscopes, disposable items, and the hands of staff were tested for *B. cepacia* contamination. Pulsed-field gel electrophoresis (PFGE) was used to compare homology in *B. cepacia* isolates.
- Results: During the outbreak, nosocomial *B. cepacia* UTI was confirmed in 71 patients. Epidemiological investigation showed that 66 patients underwent invasive urological diagnosis and treatment, while the remaining five patients underwent bedside indwelling catheterization, with all patients exposed to single-use anesthetic gel. All batches of anesthetic gel were recalled and the outbreak abated. Overall, 155 samples were collected from environmental surfaces and disposable items, and *B. cepacia* contamination was confirmed in samples from one used cystoscope and three anesthetic gels from the same batch. PFGE showed homology between 17 out of 20 *B. cepacia* isolates from patients and three isolates from the contaminated anesthetic gel. All patients achieved cure.
- Conclusion: Contaminated single-use anesthetic gel was confirmed as the source of the *B. cepacia* outbreak, with infection occurring during invasive urological diagnostic and treatments. Thus, investigations of nosocomial outbreaks of *B. cepacia* infection should consider contamination of diagnostic and treatment items used in infected patients.

III. 소독과 멸균의 실제⁶

의료관련감염 표준예방지침



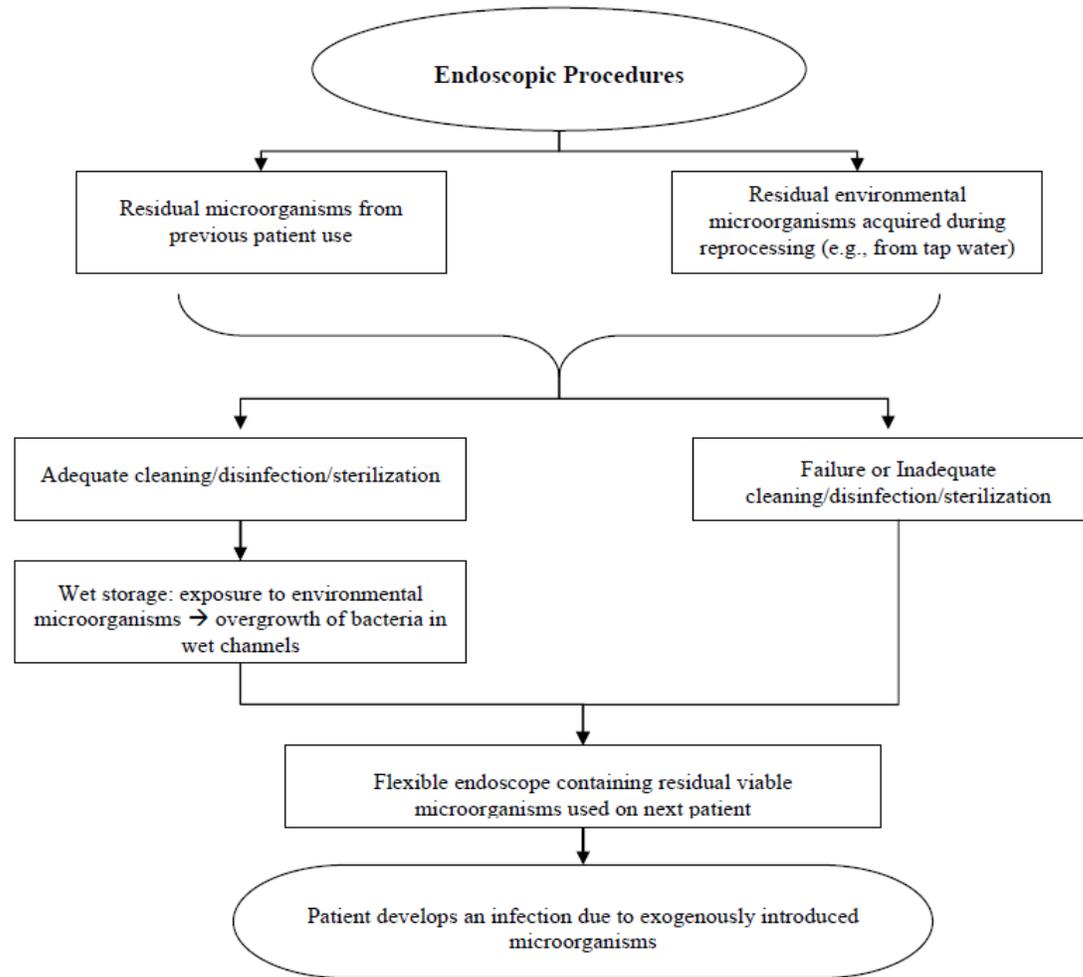
라) 초음파 젤 관리¹⁴

- ① 초음파 젤 관리와 멸균/비멸균 젤(멸균하지 않은 젤)의 사용대상에 대한 규정을 마련하고 제품의 크기와 유형을 고려하여 선택한다.
- ② 인체의 무균조직을 침범하는 시술(조직 생검 등) 시에는 멸균 젤을 사용한다.
- ③ 사용 중인 용기에 젤을 재보충(refill)하지 않는다.
- ④ 건조하고 먼지, 습기, 곤충과 설치류로부터 안전한 장소에 보관하고 오염이 의심되면 즉시 폐기한다.

An outbreak of *Pseudomonas aeruginosa* urinary tract infections following out-patient flexible cystoscopy

- The investigation of an outbreak of *Pseudomonas aeruginosa* urinary tract infections following ambulatory cystoscopies identified a damaged cystoscope contaminated by *P. aeruginosa*, and acting as a relay object. This outbreak urges to not trivialize UTI occurring after an elective cystoscopy. Patients should be advised to signal the occurrence of urologic symptoms after urologic exploration.
- Cystoscopy-related outbreaks are scarcely reported in the literature and the risk of patients' contamination through cystoscopy is poorly known. Several outbreaks occurring after bronchoscopy are associated with the use of a damaged device, inadequate disinfection and manufacturing defect. The outbreak reported herein was relayed by a cystoscope contaminated by *P. aeruginosa*, probably in biofilm attached onto the channel scratch, which allowed it to resist disinfectants.

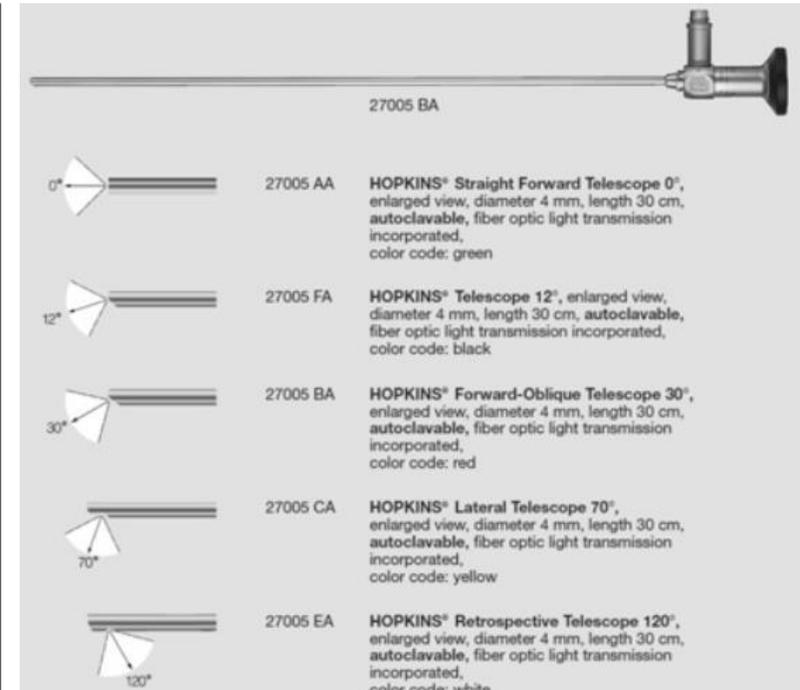
Acquisition of Exogenous Microorganisms Causing Endoscopy Related Infection



내시경

Table 3. Examples of Specifications For Flexible Endoscopes

SCOPE TYPE	INSERTION TUBE O.D. (outer diameter)	WORKING LENGTH	INSTRUMENT CHANNEL I.D. (internal diameter)
Adults			
GASTROSCOPE	9.0 mm-11.4 mm	1030 mm-1050 mm	2.8 mm-3.8 mm
DUODENOSCOPE	10.8 mm-12.5 mm	1235 mm-1250 mm	3.2 mm-4.2 mm
COLONOSCOPE	12.9 mm-13.7 mm	1330 mm-1680 mm	3.7 mm-4.2 mm
SIGMOIDOSCOPE	12.8 mm-13.2 mm	700 mm-730 mm	3.7 mm-4.2 mm
ENTEROSCOPE	10.5 mm-11.7 mm	2200 mm-2500 mm	2.8 mm-3.8 mm
BRONCHOSCOPE	5.7 mm-6.0 mm	550 mm-600 mm	2.0 mm-2.8 mm
Pediatrics			
GASTROSCOPE	5.9 mm-6.0 mm	1030 mm-1050 mm	2.0 mm
COLONOSCOPE	11.5 mm-11.6 mm	1680 mm-1700 mm	3.2 mm-3.8 mm
BRONCHOSCOPE	4.4 mm-5.1mm	600 mm	2.0 mm



연성방광경 :
2.2mm – 2.4mm / 37 – 38cm

Gastrointestinal Endoscopes A Need to Shift From Disinfection to Sterilization?

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More than 10 million gastrointestinal endoscopic procedures are performed annually in the United States for diagnostic purposes, therapeutic interventions, or both.¹ Because gastrointestinal endoscopes contact mucosal surfaces, use of a contaminated endoscope may lead to patient-to-patient transmission of potential pathogens with a subsequent risk of infection.¹

In this issue of *JAMA*, Epstein and colleagues² report findings from their investigation of a cluster of New Delhi metallo- β -lactamase (NDM)-producing *Escherichia coli* associated with

First, endoscopes are semicritical devices, which contact mucous membranes or nonintact skin, and require at least high-level disinfection.^{3,4} High-level disinfection achieves complete elimination of all microorganisms, except for small numbers of bacterial spores. Because flexible gastrointestinal endoscopic instruments are heat labile, only high-level disinfection with chemical agents or low-temperature sterilization technologies are possible.³ However, no low-temperature sterilization technology is US Food and Drug Administration (FDA)-cleared for



Multisociety guideline on reprocessing 2016 update

Prepared by: REPROCESSING GUIDELINE TASK FORCE

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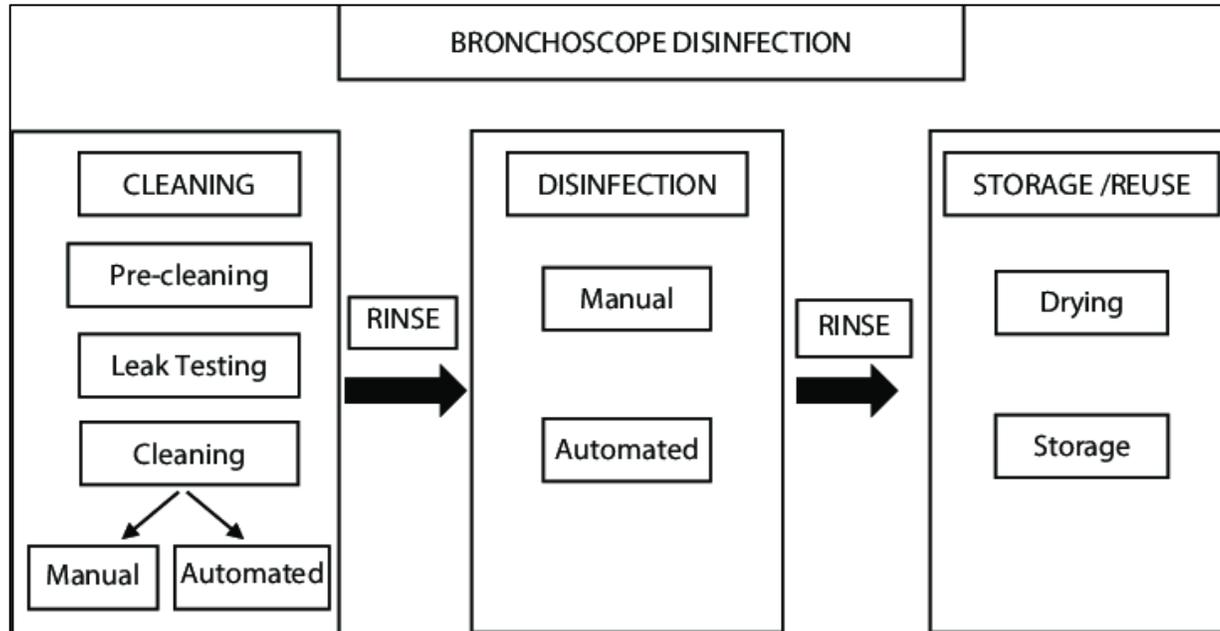
This article was reviewed and approved by the Governing (ASGE).

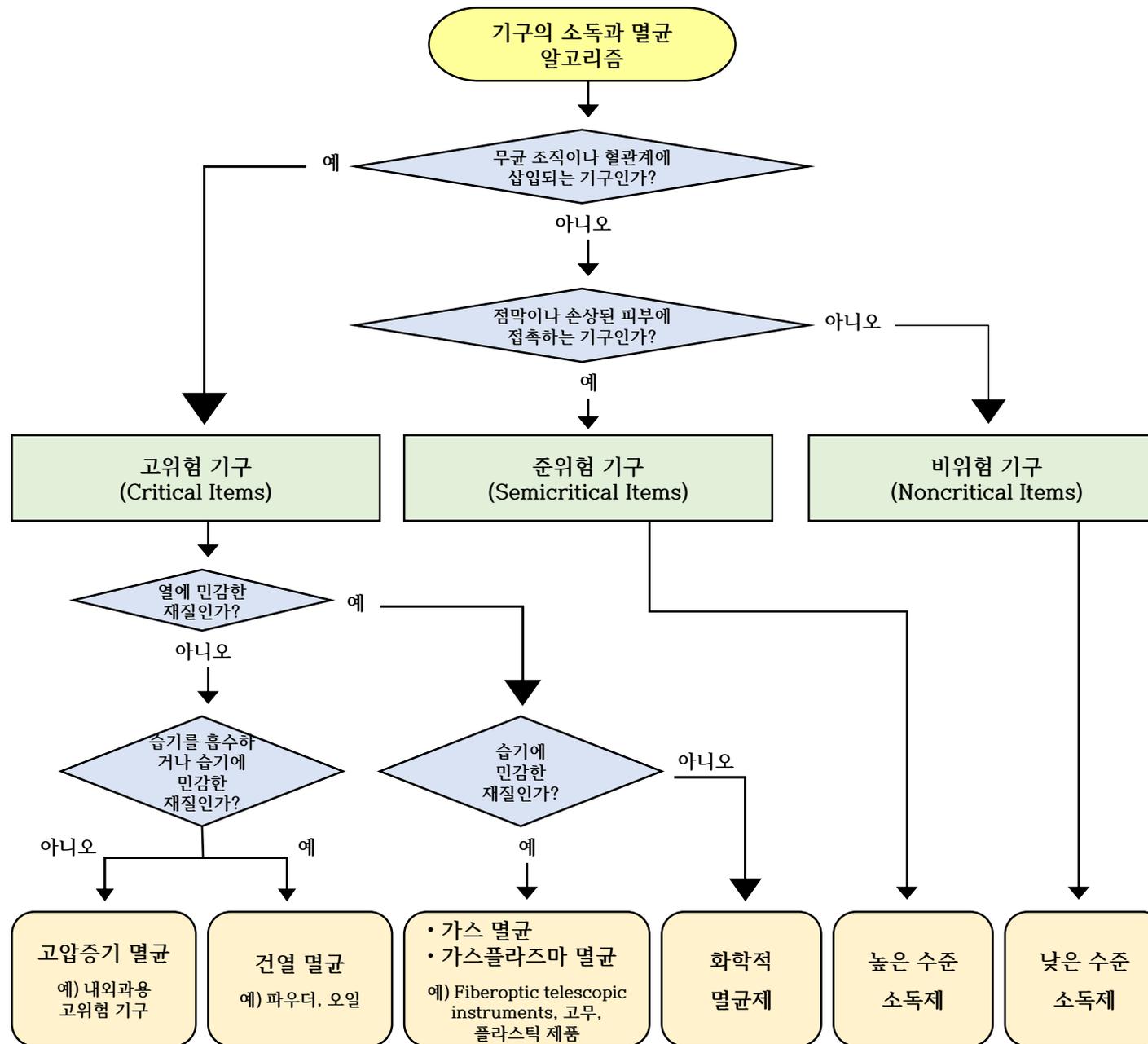
16. HLD can be performed in an automated endoscope reprocessor (AER) or using manual processes. Use of an AER is advisable and should be adopted when feasible. When an AER is used, ensure that the endoscope and endoscope components can be effectively reprocessed in the AER (eg, the elevator wire channel of duodenoscopes is not effectively disinfected by most AERs, and this step should be performed manually). Users should obtain and review FDA-cleared model-specific reprocessing protocols from both the endoscope and the AER manufacturers and check for compatibility. Category IB^{38-40,43,46,106,108,112,113}
17. If an AER is used, place the endoscope and endoscope components in the reprocessor and attach all channel connectors according to the AER and endoscope manufacturers' instructions to ensure exposure of all internal surfaces with the high-level disinfectant solution. Only approved connectors should be used. Category IB^{38,40,43,106-108}
18. If an AER cycle is interrupted, HLD or sterilization cannot be ensured; therefore, the cycle should be repeated. Category II^{40,43}
19. Because design flaws have compromised the effectiveness of AERs and can also involve endoscopes, the infection prevention staff should routinely review and document their attention to FDA advisories, manufacturer alerts, and the scientific literature for reports of endoscope and AER deficiencies that may lead to infection. Category II^{107,114-117}

내시경

Level of Processing and Reprocessing	Classification of Equipment/ Device	Examples of Equipment/Devices	Level of Processing and Reprocessing	Classification of Equipment/ Device	Examples of Equipment/Devices
<p>High-Level Disinfection The level of disinfection required when processing semicritical equipment/devices. High-level disinfection processes destroy vegetative bacteria, mycobacteria, fungi and enveloped (lipid) and non-enveloped (non-lipid) viruses, but not necessarily bacterial spores.</p>	Semicritical equipment/devices	<ul style="list-style-type: none"> • Flexible endoscopes that do not enter sterile cavities or tissues • Laryngoscopes • Bronchosopes, cystoscopes (sterilization is preferred) • Respiratory therapy equipment • Nebulizer cups • Anaesthesia equipment • Endotracheal tubes • Specula (nasal, anal, vaginal – disposable equipment is strongly recommended) • Tonometer foot plate • Ear syringe nozzles • Sonography (ultrasound) equipment/probes that come into contact with mucous membranes or non-intact skin (e.g. transrectal probes) • Pessary and diaphragm fitting rings • Cervical caps • Breast pump accessories • Glass thermometers • CPR face masks • Alligator forceps • Cryosurgery tips • Ear cleaning equipment, ear curettes, otoscope tips • Fingernail care equipment used on multiple clients/patients/residents 	<p>Sterilization The level of reprocessing required when processing critical equipment/devices. Sterilization results in the destruction of all forms of microbial life including bacteria, viruses, spores and fungi.</p>	Critical equipment/devices	<ul style="list-style-type: none"> • Surgical instruments • Foot care equipment • Implantable equipment/devices • Endoscopes that enter sterile cavities and spaces (e.g., arthroscopes, laparoscopes) • Bronchosopes , cystoscopes (sterilization preferred) • Biopsy forceps, brushes and biopsy equipment associated with endoscopy (disposable equipment is strongly recommended) • Colposcopy equipment • Electrocautery tips • Endocervical curettes • Fish hook cutters • Transfer forceps • Eye equipment, including soft contact lenses • Dental equipment including high speed dental hand pieces

연성내시경 재처리과정





- CJD 등 특수 병원체에 접촉한 기구의 경우 해당 지침을 따른다.
- 준위험 기구의 경우 최소한 높은 수준의 소독을 시행하고, 상황에 따라 멸균 처리하는 것이 더 안전할 수도 있다.

경청해 주셔서 감사합니다.