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Use of flexible endoscopes for NOTES: sterilization or high-level disinfection?

Georg O. Spaun · Trudie A. Goers · Richard A. Pierce · Maria A. Cassera · Sandy Scovil · Lee L. Swanstrom

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Abstract
Background Natural orifice translumenal endoscopic surgery (NOTES) involves the use of flexible endoscopes to perform intra-abdominal or intra-thoracic surgeries. Surgery in the operating room usually involves sterile instrumentation, whereas in the endoscopy suite high-level disinfection seems to be sufficient. Our objective was to assess the necessity for endoscope sterilization for clinical NOTES and to develop an endoscope processing protocol based on a score for the available processing options.
Methods Score and processing protocol development for clinical NOTES endoscopes was based on a comprehensive review of the available relevant literature. Options for sterilization for flexible endoscopes in the Good Samaritan Hospital, Legacy Health in Portland, Oregon, were analyzed for patient safety, potential for recontamination, cost, and validation.
Results Literature survey indicated that there is controversy surrounding the necessity for sterilization of surgical endoscopes. However, standard of practice seems to call for sterile instrumentation for surgery and it is possible to terminally sterilize flexible endoscopes. Within our institution, a score was created to rank the available sterilization options. We successfully introduced a protocol for sterilization of endoscopes for use in clinical NOTES procedures. The protocol involved mechanical cleaning and high-level disinfection per Multi-Society Guidelines, with subsequent terminal sterilization using a validated peracetic acid protocol.
Conclusions It remains controversial whether sterile instrumentation is truly needed for surgery. It is difficult but possible to terminally sterilize flexible endoscopes. We recommend sterile instrumentation for clinical NOTES until well-designed, randomized, clinical trials are available and guidelines are published.

Keywords Natural orifice translumenal endoscopic surgery · NOTES · Flexible endoscope · Sterilization · High-level disinfection

There is a fundamental distinction between disinfection and sterilization. Sterilization describes a process that destroys all forms of microbial life, whereas disinfection describes a process that eliminates most pathogenic microorganisms, with the exception of some bacterial spores and infectious proteins [1, 2]. The United States Food and Drug Administration Agency (FDA) defines high-level disinfection as necessary exposure time for a sterilant to achieve a 6-$\log_{10}$ kill of an appropriate Mycobacterium species. Instruments that usually enter sterile cavities during surgery are defined as critical items and should be sterilized [1]. If instruments are used only endoluminally, they are considered semicritical items and high-level disinfection was found to be sufficient [1, 3–7]. In current natural orifice translumenal endoscopic surgery (NOTES) practice, dual-channel endoscopes or the single-use TransPort™ Endosurgical Operating Platform (USGI Medical, San Clemente, CA; Fig. 1) have been used for clinical cases [8]. The TransPort™ still requires the use of

G. O. Spaun (✉) · T. A. Goers · R. A. Pierce · M. A. Cassera · S. Scovil · L. L. Swanstrom
Legacy Health, Portland, OR, USA
e-mail: georg.spaun@gmail.com

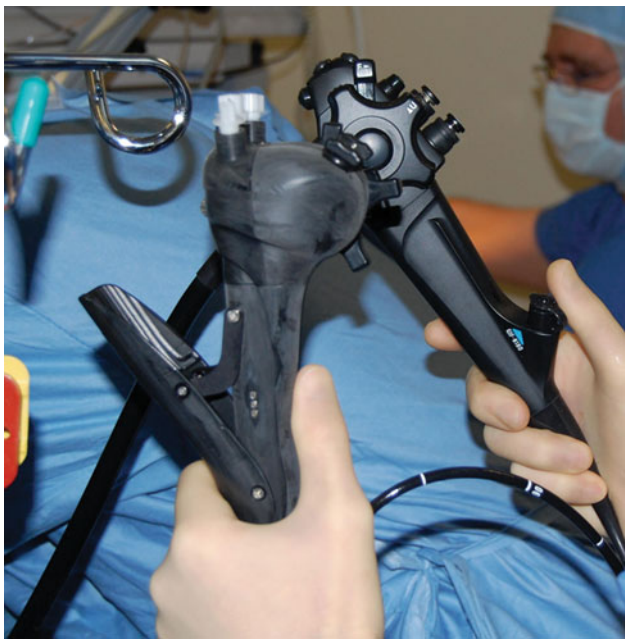

Fig. 1 TransPort™ Endosurgical Operating Platform (left; USGI Medical, San Clemente, CA), which has been used for clinical transgastric cholecystectomies, requires the use of a flexible endoscope (right; GIF N-180; Olympus, Tokyo)

a flexible endoscope (GIF N-180; Olympus, Tokyo, Japan; Fig. 1) for visualization. Because NOTES involves the use of flexible endoscopes to perform intra-abdominal or intrathoracic surgeries, the current concept of sterile instrumentation for NOTES may need to be reconsidered or protocols for meeting current surgical standards created.

Standard flexible endoscope processing within the United States usually follows the U.S. Multi-Society guidelines, which provide recommendations for achieving high-level disinfection [1, 9–12]. Briefly, standard endoscope-reprocessing is a three-stage process that includes:

1. *Pre-processing*—mechanical cleaning of the endoscope and its detachable components using a detergent solution and brushes.
2. *Processing*, or high-level disinfection, of the endoscope using an FDA-approved liquid chemical germicide followed by thorough water rinsing to remove residual chemicals from the instrument (Fig. 2).
3. *Post-processing*—includes proper handling and storage of the endoscope. This third and final step also includes drying the endoscope and its internal channels after terminal water rinsing.

An additional stage of scope preparation is necessary to provide truly sterile endoscopes.

This study was designed to assess necessity, evaluate and rank options for flexible endoscope sterilization, and propose a protocol to be used for clinical NOTES.

Fig. 2 High-level disinfection performed in the endoscopy suite

Methods

A comprehensive review of the available relevant literature was performed, including the CDC (Center for Disease Control and Prevention) Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 [1, 12]. This is a summary of most of the available literature, including 1,035 references. We evaluated options that are currently available for endoscope sterilization in the United States (Table 1) and analyzed them for the potential for recontamination, cost, and available validation. A score was developed to rank the available options for use in our facility (Table 2). Higher risk for recontamination and higher cost resulted in lower ranking number. Potential for recontamination was determined by the necessity of manipulating the endoscope without sterile cover after the sterilization process. Cost was calculated by summing depreciation of machinery, regulatory fees, maintenance, labor, disposables, and chemicals used for sterilization (Tables 3, 4, 5). The score displayed in Table 6 was calculated by adding the ranking number of the risk of recontamination to the ranking number of cost (ranking see Table 2).

Based on the score, a protocol for the sterilization of flexible endoscopes for the NOTES procedures was created. The protocol involved mechanical cleaning and high-level disinfection per Multi-Society Guidelines with subsequent terminal sterilization. Methods for transportation and handling of the sterile endoscope were created.

Results

A survey conducted of the current relevant literature reveals controversy around the absolute necessity for sterilization of surgical instruments. Standards of practice seem to call for sterile instrumentation for surgical procedures and high-level disinfection for flexible intraluminal endoscopy. With

Table 1 FDA-approved sterilants

Acecide high-level disinfectant and sterilant	8.3% hydrogen peroxide, 7.0% peracetic acid	5 h at 25°C
Aldahol III high-level disinfectant	3.4% glutaraldehyde, 26% isopropanol	10 h at 20°C
Banicide Advanced for sterilization and high-level disinfection	3.5% glutaraldehyde	10 h at 25°C
Sporicidin sterilizing and disinfecting solution	1.12% glutaraldehyde, 1.93% phenol/phenate	12 h at 25°C
Rapicide high-level disinfectant and sterilant	2.5% glutaraldehyde	7 h 40 min at 35°C
Cetylcide-G concentrate and diluent concentrate	3.2% glutaraldehyde	10 h at 20°C
MedSci 3% Glutaraldehyde	3% glutaraldehyde	10 h at 25°C
EndoSpor plus sterilizing and disinfecting solution	7.35% hydrogen peroxide, 0.23% peracetic acid	3 h at 20°C
Sporox sterilizing and disinfection solution	7.5% hydrogen peroxide	6 h at 20°C
Peract 20 liquid Sterilant/disinfectant	1.0% hydrogen peroxide, 0.08% peracetic acid	8 h at 20°C
Procide 14 N.S.	2.4% glutaraldehyde	10 h at 20°C
Omnicide Long-Life Activated Dialdehyde solution	2.4% glutaraldehyde	10 h at 20°C
Omnicide Plus	3.4% glutaraldehyde	10 h at 20°C
Metricide Plus 30 Long-Life Activated Dialdehyde Solution	Research, Inc. 3.4% glutaraldehyde	10 h at 25°C
Metricide 28 Long-Life Activated Dialdehyde solution	2.5% glutaraldehyde	10 h at 25°C
Metricide Activated Dialdehyde solution	2.6% glutaraldehyde	10 h at 25°C
Cidex Activated Dialdehyde solution	2.4% glutaraldehyde	10 h at 25°C
Cidex Formula 7 Long-Life Activated Dialdehyde solution	2.5% glutaraldehyde	10 h at 20–25°C
Cidex Plus 28-day solution	3.4% glutaraldehyde	10 h at 20–25°C
Wavicide - 01	2.5% glutaraldehyde	10 h at 22°C
Steris 20 Sterilant (Steris System 1)	0.2% peracetic acid	12 min at 50–56°C
ETO (ethylene oxide) gas sterilization	Ethylene oxide	20 h

Extracted from: www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/UCM133514

Table 2 Score calculation for endoscope sterilization

Ranking	Risk of recontamination 1 = highest risk	Cost 1 = highest cost
1	Prolonged soak	ETO
2	Steris System 1	Prolonged soak
3	ETO	Steris System 1

Potential for recontamination was determined by the necessity of manipulating the endoscope without sterile cover after the sterilization process. Cost was calculated by summing depreciation of machinery, regulatory fees, maintenance, labor, disposables, and chemicals used for sterilization. Only validated methods of sterilization were included in the analysis. Prolonged soak = prolonged soak in high-level disinfectant/sterilant; Steris = peracetic acid protocol in Steris System 1; ETO = ethylene oxide

Table 3 Prolonged soaking in sterilant

	Cost
Sterile gloves	$5.82
Sterile gown	$15.12
Sterile container	$1.00
Mask/shield	$3.66
Syringe	$1.86
Cidex (*example*)	$0.52
Sterile water	$6.78
Labor	$24.41
Total cost	$59.17

Costs, including labor, were calculated on a per scope basis; soaking in sterilant, three times rinsing the channels under sterile conditions using sterilant, consecutive rinsing with sterile water under sterile conditions (requires five sets of sterile gloves and gowns). The cost for the sterilant was found to be <1% of the total cost for the prolonged soaking sterilization method

current technology it is possible but cumbersome to terminally sterilize flexible endoscopes. All substances that have FDA clearance for sterilization of endoscopes have been evaluated and are listed in Table 1.

The three possible sterilization techniques available for human use in the United States are: prolonged soaking in high-level disinfectant/sterilant, automated liquid sterilization, and gas sterilization using ethylene oxide (ETO). Two additional sterilization modalities are currently being developed: hydrogen peroxide gas vapor sterilization (e.g., STERRAD®, Ethicon Inc., Somerville, NJ), and ozone sterilization (TSO3 Inc., Dalton, Quebec, Canada) [13, 14]. At this time, both are unavailable for clinical use with flexible endoscopes in the United States.

Prolonged soak in high-level disinfectant/sterilant

The cost for the sterilant was found to be <1% of the total cost for the prolonged soaking sterilization method in our

Table 4 Steris System 1 sterilization

	Cost
Sterile gloves	$0.97
Sterile gown	$2.52
Mask	$0.61
Single-use gloves	$0.01
Container sterilization	$1.25
Sterilant	$7.98
Indicator	$0.88
Maintenance	$8.00
Labor	$1.25
Total cost	$23.47

Costs for using the Steris System 1; purchasing costs of the Steris System 1 have been included in the maintenance costs

Table 5 ETO sterilization

	ETO 100%
Cost per load	$16.50
Labor	$15.00
Other costs	$75.00
Total cost	$106.50

Costs calculated for using ETO sterilization (100% ETO). "Other costs" include depreciation, regulatory standards, and maintenance

Table 6 Score results of available sterilization options

	Calculated score
Steris System 1	5*
ETO	4
Prolonged soak	3

Results of the scoring system applied to our institution. Peracetic acid sterilization (Steris System 1) achieved the highest score. ETO sterilization and the individual soaking sterilization options scored lower and were found to be less practical in our system. However, ETO sterilization has the lowest risk for recontamination after the sterilization process. * Since January 2009, Steris Inc. is selling the System 1 processor in the United States on a "one for one" replacement basis only. Prolonged soak = prolonged soak in high-level disinfectant/sterilant; Steris = peracetic acid protocol in Steris System 1; ETO = ethylene oxide

institution. The sterilization process is lengthy and therefore not practical. In our evaluation, the risk of recontamination was found to be the highest for this sterilization method. The cost for the soak-sterilization was ranked second. Table 3 gives an overview of the costs for this sterilization option. The complete list of FDA-approved sterilants is listed in Table 1; the FDA maintains an updated list online: www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/UCM133514.

Steris System 1

The automated Steris System 1 (Steris Inc., Mentor, OH) claims sterilization capability using a liquid chemical sterilization method (peracetic acid) (Fig. 3). It uses a just-in-time method much like flash-steam sterilization with the advantages of permanent endoscope availability in the endoscopy suite and short sterilization time. The cost for this sterilization method was ranked lowest in our evaluation and the risk for recontamination second. Unfortunately, since January 2009, Steris Inc. is selling the System 1 processor in the United States on a "one for one" replacement basis only. FDA approval for an updated System 1 is pending. Table 4 breaks down the total cost for this option.

Ethylene oxide gas sterilization

All flexible endoscopes are compatible with ETO, which provides true sterilization. Endoscopes sterilized with this method are dry and therefore easily packaged and transported to the sterile field as a sterile instrument. Therefore, the risk of recontamination was found to be the lowest for ETO sterilization, but cost was found to be the highest. However, there are problems with ETO; it is being phased out in many healthcare facilities due to safety and environmental concerns and, therefore, has limited availability. ETO was found to be an impractical option at our institution, because it is no longer performed in the hospital and would result in unrealistically long turn-around time for scope sterilization. Table 5 breaks down the cost for running ETO sterilization.

Table 6 displays the ranking results of our score based on the calculation shown in Table 2.

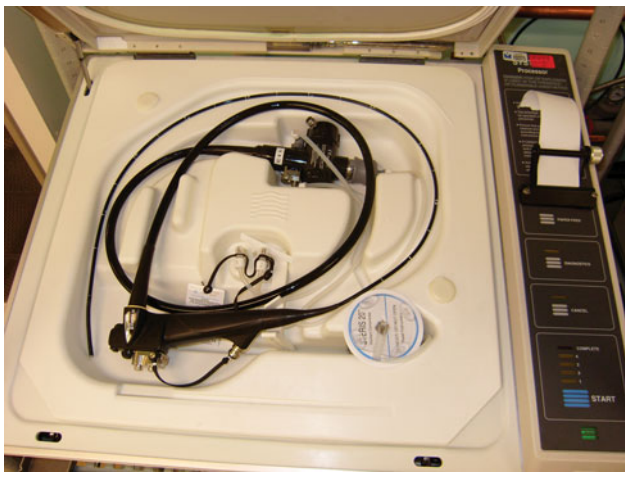

Fig. 3 GIF-N180 endoscope (Olympus, Tokyo, Japan) in the C1160 Universal Processing Tray attached to the QLC1725 Quick Connect (both, Steris Inc., Mentor, OH)

We successfully introduced the following protocol for sterilization of endoscopes for use in clinical NOTES procedures in our institution. This protocol takes into consideration issues such as potential for recontamination, cost, and validation availability. Implementation involved coordination between Minimally Invasive Surgery operating rooms, Endoscopy Services and Surgical Services.

- Endoscopy services provides standard three-stage endoscope processing (high-level disinfection).
- Endoscopes are stored afterwards in closed cabinets.
- Two hours before a scheduled NOTES, a flexible endoscope is delivered to the central sterilization unit (Surgical Services), where sterilization is performed using the Steris System 1 (Fig. 3).
- The sterile endoscope has to be removed from the sterilization container under sterile precautions (Fig. 4A), is placed in a sterile container with lid (Fig. 4B), and is delivered through the sterile core to the operating room (Fig. 4C). This step is the weak spot of the procedure because there is a risk of recontamination.
- Circulating nurse assists scrub nurse to unpack the sterile endoscope when the operator is in the room.
- Accessories, such as water bottle, lid, and tubing, are autoclaved and delivered sterile to the operating room (Fig. 5).
- A 0.003-micron filter (LF410, Airgas Inc, Radnor, PA) is used to remove sub-micron-size particulates from endoscopic CO_2 insufflation.

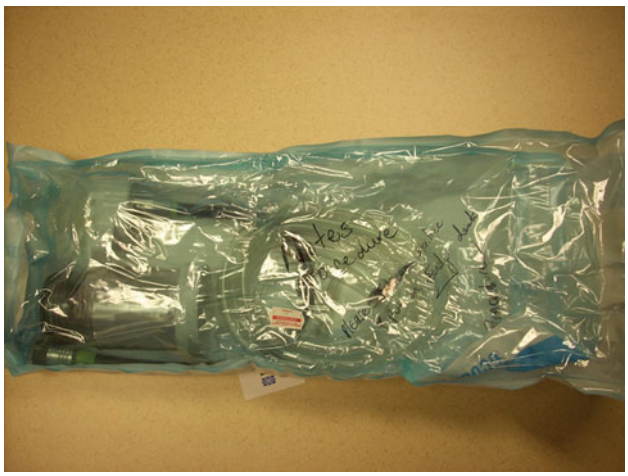

Fig. 5 Steam sterilization is performed for water bottle, lid, and tubing

Discussion

NOTES is a promising emerging technology and its successful continued development relies on maintenance of basic surgical principles. One of these principles is the use of sterile instrumentation for abdominal or thoracic surgery [1]. We therefore advocate meeting this standard when performing NOTES. The protocol described provides standard three-stage processing, including meticulous manual cleaning, high-level disinfection, and drying/storage [7, 15]. This allows for the endoscopes to be available in the daily endoscopy suite routine and ensures leakage testing, mechanical cleaning, and washing process right after the procedures. Ahead of the scheduled NOTES procedure, the endoscope is sterilized and delivered sterile to the operating room.

ETO sterilization theoretically would be the preferred sterilization method because the sterile endoscope can be delivered from the sterilization unit to the operating room as a closed, sterile package. However, it is time consuming, expensive, and not available in many facilities, including ours, due to environmental and safety concerns. This flammable, explosive, and potentially carcinogenic gas can be used as 100% ETO or in an 88/12 mix [16].

The Steris System 1 offers a relatively inexpensive, partially automated, and environmentally friendly sterilization option using a 0.2% concentration peracetic acid.

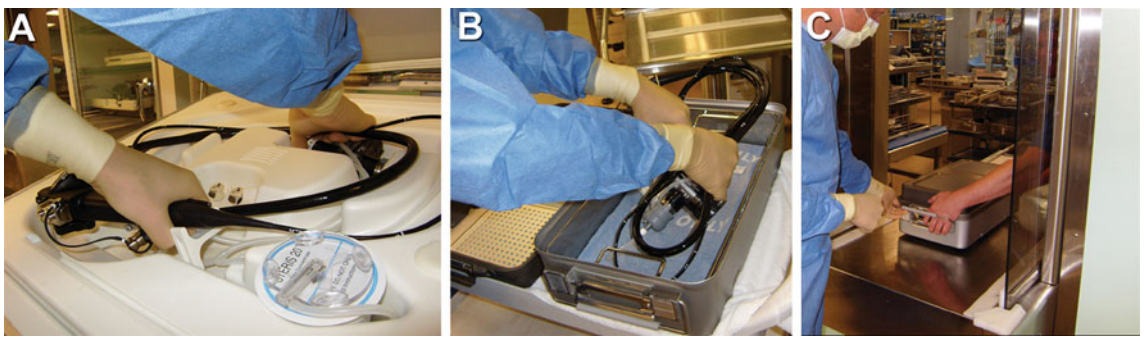

Fig. 4 Sterile handling of the processed endoscope after sterilization in Steris System 1. **A** The C1160 Universal Processing Tray is an open container and holds potential for recontamination after sterilization. **B** Endoscope is placed in sterile container after sterilization. **C** Closed container is delivered through the sterile core to the operating room

However, since January 2009, Steris Inc. is selling the System 1 processor in the United States on a "one for one" replacement basis only. Steris Inc. submitted a new 510(k) premarket notification for an updated System 1 to FDA on January 5, 2009 [17]. Besides the regulatory issues, Steris System 1 also has some disadvantages for endoscope sterilization. Damage to the endoscope has been reported sporadically [18]. The endoscope is moist after the sterilization process when delivered to the operating room. After the sterilization process, the endoscope has to be removed under sterile precautions from the system, which holds a potential for recontamination and is a significant disadvantage compared with ETO processing (Fig. 4A–C). Steris Inc. provides only validation for sterilization of the GIF N-180 endoscope using the QLC1725 Quick Connect in the C1160 Universal Processing Tray, which is an open container (both; Steris Inc.; Fig. 3). In our lab, we have processed the GIF N-180 endoscope using a modified Y-adapter linking different Quick Connects in the C1140 Flexible Endoscope Processing Tray (Fig. 6). This modified method for processing has the theoretical advantage that the recontamination risk can be reduced because of the use of a closed sterilization container. However, to date Steris Inc. has not validated this modified technique.

Surprisingly, the prolonged soak protocols were found to be more expensive than Steris System 1. Supervision of the soaking process is required by staff, frequent handling of the instruments is required, rinsing and drying after soak is difficult to perform sterile, and has the highest risk of recontamination in our evaluation.

Flexible endoscopes are extremely difficult to sterilize because of their design and cyclical exposure of patients' use and reprocessing, which can lead to an accumulation of organic material (build-up biofilm) in the instrument channels [19]. Biofilm formation represents a protected mode of growth that allows cells to survive in hostile environments [20, 21]. A complete kill of microbes in a biofilm is difficult to achieve and even more so in build-up biofilm in endoscope channels [19, 22, 23]. Endoscopes are usually much more heavily contaminated than standard surgical instruments, carrying a bioburden ranging from 10^5 colony forming units (CFU)/ml to 10^{10} CFU/ml [12, 24–26]. Therapeutic endoscopes have been shown to be even more heavily contaminated than diagnostic endoscopes [23]. It has been repeatedly shown that manual endoscope cleaning is critical for the success of the reprocessing procedure [9, 24–26]. Manual cleaning becomes even more important with increased complexity of surgical instrument design; reductions of the level of microbial contamination by 4–6 $\log_{10}$ have been shown by cleaning only [11, 27].

Fig. 6 Experimental processing of the GIF N-180 endoscope using a modified Y-adapter linking parts of different Quick Connects in the C1140 Flexible Endoscope Processing Tray (not validated by Steris Inc.)

The common practice of storing endoscopes—uncovered and hanging side by side in closed cabinets in the endoscopy unit—is very different and cannot be compared to the storage of sterile packed surgical instrumentation [15, 28]. Endoscopes often are handled in the endoscopy unit using single-use gloves packaged in multi-unit boxes, so sterile handling of the processed endoscope is not granted. Endoscopes stored in nonsterile environments are by definition, contaminated [29]. Independent of the processing method chosen for endoscope disinfection/sterilization, staff should handle the endoscopes used for NOTES like surgical instrumentation (gowns, masks, sterile gloves, etc.) and avoid recontamination before use.

Accessories, such as water bottle, lid, and tubing, can be steam sterilized (autoclaved), which is safe, cheap, and available in all surgical departments (Fig.5) [7, 15].

CO_2 delivered in pressurized containers and especially the necessary pressure reduction valves are not sterile [30]. Also, rust, metal filings, and debris can be found on filters placed distal to the insufflation regulator [30]. Therefore, laparoscopic insufflators use built-in filter systems. An equivalent to this filter is necessary to achieve sterile CO_2 insufflation through an endoscope and would need to be added to the endoscopic tower.

As review of the literature indicated, it is still under debate whether sterile instrumentation is truly needed for surgery. This argument, based on older studies and membership surveys, is mainly out of concern for damaging expensive surgical instrumentation during the process of sterilization [18, 26, 31–36]. However, the CDC guidelines state that "*laparoscopes, arthroscopes, and other scopes that enter normally sterile tissue should be sterilized before each use; if this is not feasible, they should receive at least high-level disinfection*" [1]. If future NOTES procedures

will be performed with only high-level disinfected instruments, it should be stated so in the informed consent.

Possibly more rigorous concepts than standard sterilization should be considered when taking into account diseases, such as Creutzfeldt-Jakob disease (CJD) and other transmissible spongiform encephalopathies [37]. Proteinaceous infectious agents (prions) seem to transmit these degenerative neurologic disorders. The current recommendation is to quarantine or incinerate surgical instrumentation after contact with contaminated patients, which is expensive and cumbersome [7, 38]. Prions are unusually resistant to disinfection by conventional chemical high-level disinfectants/sterilants [13, 39]. Variant Creutzfeldt-Jakob disease (vCJD) seems to be mainly transferred by consumption of beef products containing the bovine spongiform encephalopathy agent [38]. However, unlike CJD, the prions associated with vCJD can be detected in the lymphoid tissue of affected individuals (thymus, tonsil, spleen, appendix, and possibly the ileum and rectum) [37].

NOTES is breaking barriers in the surgical field but is currently in a weak position to challenge the widely accepted standard of practice of sterile instrumentation for surgical procedures; even more so in the dawn of newly discovered infectious agents. Earle H. Spaulding, Professor for Microbiology and Immunology, stated in 1978, "*Finally, in reaching a decision on disinfection vs. sterilization of endoscopes, the operator must assess the human factor. Can you depend upon the person who cleaned and disinfected that instrument after it was last used? Sometimes this is the most difficult question of all*" [40].

Conclusions

Although it remains controversial whether sterile instrumentation is truly needed for surgery, sterility remains a cornerstone of modern surgical practice. It is difficult, but possible, to terminally sterilize flexible endoscopes and deliver them sterile to the operating field using a carefully designed protocol. We recommend sterile instrumentation for clinical NOTES until well-designed, randomized, clinical trials are available and guidelines are published.

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