

IS UNIVERSAL SCREENING OF INDIVIDUALS FOR HBV, HCV AND HIV BEFORE ENDOSCOPY JUSTIFIED? AN AUDIT OF THE CURRENT PRACTICES

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ABSTRACT

Objective: To find out the current practices of sterilization and decontamination of endoscopy equipment, and to compare them with the current practical guidelines in rest of the world.

Material and Methods: This was a retrospective study carried out from January 2014 to December 2014 in the Departments of Medicine HMC, KTH, Peshawar. All the patients scheduled for endoscopy are screened for any evidence of Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) and Human Immunodeficiency Virus (HIV) by third generation ELISA test. The approximate cost of these screening tests from the hospital main laboratory is Rs 650 and it is between Rs 900 to 3000 from the outside private laboratory facilities. The endoscope is soaked in a decontaminant solution for 30 mins in the morning before the start of the procedures. The endoscope is washed with water and air dried. In between the procedures, the endoscope is wiped cleaned with a gauze piece soaked in saline and then introduced in another patient.

Results: As all the patients are screened for any evidence of HBV, HCV and HIV, it is presumed that the iatrogenic infection due to endoscope would be negligible. Universal screening for the evidence of these infections comes at average Rs 1000 per patient as compared to Rs 35 for the endoscope cleaning with the cleansing and rinsing of all the channels of the endoscope with 2% glutaraldehyde solution (Cidex, Johnson and Johnson Medical Inc., Arlington, TX) for 15 minutes through automated Endodisinfector followed by rinsing the channels with water and later purging with air.

Conclusion: Timely intervention in terms of Endodisinfection and appropriate training of the staff in sterilization and disinfection of the endoscopes as per international guidelines is suggested before it becomes a human rights issue.

Key Words: Endoscopy, Endodisinfector, Audit.

INTRODUCTION

Upper and lower gastrointestinal (GI) endoscopy is frequently done across the globe for therapeutic and diagnostic purposes. Only in the United States, greater than 10,000,000 gastrointestinal endoscopic procedures are performed each year.¹ All invasive GI procedures involve close contact between the subject mucous membrane and endoscope. Any failure to properly clean, disinfect or sterilize medical equipment according to the prescribed guidelines carries a huge risk of iatrogenic infection resulting from the breach of the host barriers.²

The Food and Drug Administration (FDA) recommends exposure of GI endoscopes to 2.4% Glutaraldehyde solutions heated at 25°C for 45 minutes. Simultaneously, the American Gastroenterological As-

sociation (AGA), American Society for Gastrointestinal Endoscopy (ASGE) and the Society of Gastroenterology Nurses and Associates (SGNA) have endorsed a reprocessing guideline, that emphasizes manual preleasing and recommends exposure to 2.4% Glutaraldehyde solution at room temperature for atleast 20 minutes.³

The Canadian Association of Gastroenterology (CAG) and the Public Health Agency of Canada in year 2010 have developed Canadian Guidelines for the reprocessing of the flexible GI endoscopes. The guidelines consist of seven sections, including administrative recommendations, recommendation for endoscopy and endoscopy equipment decontamination, endoscopes and accessories reprocessing, design of endoscopy unit, quality management, investigation and management of outbreaks, and classic and variant Creutzfeldt-Jakob Diseases.⁴ All the endoscopes require high-level disinfection. High level disinfection is defined as the destruction of all vegetative microorganisms, mycobacterium, small or non-lipid viruses, fungal spores and some, but not all, bacterial spores.⁴

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It has been well recognized for many years that because of the complex, fragile construction of endoscopes and because of the difficulty of decontaminating them, endoscopy serves as a potential source of iatrogenic infection. It has been investigated in the past and rigorous cleaning equipment and protocols have been devised over years. The risks of transmission due to endoscopes remain minimal in the developed world. The available data of iatrogenic infections due to diagnostic endoscopic procedures remain very less. It is considered a safe procedure when all the guidelines and the protocols for the cleaning of the endoscope are rigorously followed. The aim of our study was to find out the current practices of sterilization and decontamination of endoscopy equipment in our setup and to compare them with the current practical guidelines in rest of the world.

MATERIAL AND METHODS

This was a retrospective study carried out from January 2014 to December 2014 in the Departments of Medicine Hayatabad Medical Complex (HMC) and Khyber Teaching Hospital (KTH), Peshawar. All the patients scheduled for endoscopy were screened for any evidence of Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) and Human Immunodeficiency Virus (HIV) by third generation ELISA test.

The approximate cost of these screening tests from the hospital main laboratory is Rs 650 and it is between Rs 900 to 3000 from the outside private laboratory facilities. Any patient who is found to be incidentally infected with any of these viruses is sent over to Gastroenterology Unit, Hayatabad Medical Complex, Peshawar for upper or lower GI endoscopy.

All the patients who are found negative for any of these infections are made Nil by mouth from midnight and shifted to the endoscopy unit for procedure in the morning. The endoscope is soaked in a solution containing Bis (3-aminopropyl) dodecylamine 19.20 g, Didecylidimethylammonium chloride 2.30 g, Tensides, complexing agent and perfume for 30 mins in the morning before the start of the procedures. The solution standing time is upto 14 days and is changed after every ten days. The endoscope was then washed with water and air dried. Microbiological activity and acting time of solution is given in table according to manufacturer. In between the procedures, the endoscope is not soaked again in the solution. It is just wiped cleaned with a gauze piece soaked in saline and then introduced in another patient.

RESULTS

The current practice in the Endoscopy suite is to wipe clean the endoscope with a gauze soaked in normal saline and then introduce it in another patient.

As all the patients are screened for any evidence of HBV, HCV and HIV, it is presumed that the iatrogenic infection due to endoscope would be negligible.

We have only calculated the cost aspect of such approach and have found a huge difference in both the approaches. Universal screening for the evidence of these infections comes at average Rs 1000 per patient as compared to Rs 35 for the endoscope cleaning with the cleansing and rinsing of all the channels of the endoscope with 2% glutaraldehyde solution (Cidex, Johnson and Johnson Medical Inc., Arlington, TX) for 15 minutes through automated Endodisinfector followed by rinsing the channels with water and later purging with air.

There remains no need of universal screening of all the patients for evidence of HBV, HCV or HIV if the endoscope is cleaned in line with the international recommendations. Universal pre cleansing as per the international laid down protocols can reduce the cost burden besides minimizing the risk of iatrogenic spread of infections.

The constitution of solution presently used in Endoscopy Department of KTH for soaking endoscope in the morning before the procedures is shown below:

Spectrum (with load)	15 Min	30 Min	60 Min
Bacteria and fungi ¹	0.25		
Mycobacteria ²	2.0%	1.0%	0.5%
Spores ³	2.0%	1.0%	
Viruses ⁴ HCV	0.25		
Vaccinia virus	1.0%	0.5%	
HBV/HIV	1.0%	0.5%	
SARS/ Herpes/influenza/ H1 N1/H5N1	1.0%	0.5%	

1. Instrument disinfection according to VAH/DGHM. Tested according to EN 13727. EN 13624. EN 14561 and EN 14562.
2. M. terrae, M. avium; tested according to EN 14348.
3. Spores tested according to EN 13704.
4. Viruses tested according to DW/RKI/EN 14476.

DISCUSSION

Both Upper and Lower GI Endoscopy have found an immense role in the medical practice primarily because it is minimally invasive interventional procedure for pancreatobiliary and GI disorders.⁵ More than 10 million GI endoscopies are reported to be performed every year in the United States.⁶ With time the need of the endoscopic procedures both diagnostic and therapeutic are increasing.

In the better developed parts of the world the GI endoscopy is performed more of as a routine procedure.

ture,⁷ however the availability of these services is limited in the lesser developed countries and is only available in few centres.⁸ Sound understanding and knowledge regarding infection control and its application to GI endoscopy is necessary. Adopting such precautions can help prevent the potential spread of the infection through the endoscope.

Disinfection or sterilization of endoscope is done with a liquid chemical sterilant in the following 5 steps, after leak testing is performed; (1) Clean: mechanically clean internal and external surfaces of endoscope, including brushing internal channels and flushing all internal channels with water and enzymatic cleaner; (2) Disinfect: endoscope is immersed in high-level disinfectant (or chemical sterilant), disinfectant is perfused into all accessible channels, including the suction/ biopsy channel and the air/water channels and exposes endoscope for the recommended time to specific products; (3) Rinse: endoscopic and all its channels are rinsed with sterile water, filtered water or tap water; (4) Dry; insertion tube and inner channels are raised with alcohol and dried with forced air, after disinfection and before storage, and (5) Store: The endoscope is stored by vertically hanging to prevent recontamination and promote drying. High level disinfection (HLD) is typically achieved in less time by soaking the instrument in Liquid Chemical Germicide (LCG). Although high numbers of bacterial spores may not necessarily be inactivated when used as a disinfectant, 2% Glutaraldehyde solution is highly sporocidal even during soaking times as short as 10 minutes.^{9,10}

Fortunately the reported incidence of endoscope-associated infection is very low, which is approximately 1 in 1.8 million endoscopic procedures.¹¹ Nevertheless unrecognized and unreported outbreaks have been reported over the years, the number is highly likely be an underestimate. Most reported organisms in outbreaks are water borne or enteric bacteria, such as *Pseudomonas*, *Salmonella*, and *Mycobacteria* species. Despite the low incidence of infection, endoscopes are often implicated in device-related healthcare associated outbreaks worldwide. HBV and HCV infection transmission have been attributed to GI endoscopy, but no case of HIV transmission has been reported.¹²

In one recent national survey in the United States, 116 of 2030 responders indicated that endoscopy-transmitted infections had occurred in their institution,¹³ suggesting that risk of transmission may be higher than generally realized. Recent epidemiological surveys of endoscopy units have suggested that failure to comply with recommended guidelines is relatively common.^{14,15} The most common reason for endoscopy related infection remain the endoscope cleaning staff not strictly adhering to the recommended guidelines^{16,17}.

Spach et al reviewed the English literature on the possible transmission of infections by gastrointestinal endoscopy and bronchoscopy. Fortunately, the numbers of papers reporting transmission of infection by upper GI endoscopy is very small, and most cases have been associated with improper disinfection technique.¹⁸

In a recent review of the published medical literature and the US FDA database, only 35 cases of transmission of infection during GI endoscopy have been reported in the last decade, all of which have been associated with breaches in reprocessing protocols.²⁰ Various iatrogenic infections due to endoscopes have been reported all over the world notably HBV, HCV, *Salmonella*, *Pseudomonas* and *H Pylori*.

A landmark study comprised of 8260 patients who had undergone upper GI endoscopy and were tested for HCV seropositivity before endoscopy and 6 months after the procedure. Fortunately no cases of HCV infection as evident from the seroconversion were found. This large study is the best evidence to show that appropriate endoscope reprocessing if performed effectively in the community prevents the transmission of hepatitis C virus.¹² There are several prospective studies in which patients were followed for serologic evidence of HBV transmission following endoscopy. In a study, a total of 223 patients were followed in whom endoscopy was performed with an endoscope known to have been used on a patient with HBV. All of these patients were followed for 6 months. There were no cases of HBV seroconversion reported in any of these patients.¹⁹

Since 1974, there have been 48 cases of endoscopic transmission of various *Salmonella* species.²¹⁻²⁸ Each of these cases has been associated with at least one breach in currently accepted reprocessing guidelines. The most frequent breach noted was failure to mechanically clean the internal instrument channel besides the use of an inappropriate disinfectant, or an inadequate disinfection time.

Because of the vigorous and standardized disinfection protocols laid by the ASGE, SGNA, and the British Society of Gastroenterology (BSG), since 1988 no new cases of *Salmonella* Infections due to Endoscope have been reported.^{29,30} Unlike *salmonella*, which does not appear to be a persistent infection control problem, *Pseudomonas aeruginosa* continues to pose a challenge to endoscope reprocessing, and is the most commonly reported organism responsible for transmission of infection during endoscopy. There have been 216 reported cases of *Pseudomonas aeruginosa* transmission.³¹⁻⁴³

Twelve confirmed cases of iatrogenic transmission of *H Pylori* due to endoscope have been reported. All of these cases have been attributed to poor disinfection.

tion techniques.⁴⁴⁻⁴⁵ Since the introduction of cleaning and disinfection protocols, the incidence has further declined. The Endoscopy suite in Khyber Teaching Hospital, lacks Endodisinfector using the correct cleaning techniques in line with the international recommendations. Rather the reliability is laid on protocol of finding patients who are not infected with either of the HBV, HCV or HIV infections and presumption that no iatrogenic infection due to the procedure would be introduced. This approach is found to be nonscientific and cost ineffective.

CONCLUSION

Universal screening of all the patients before the endoscopic procedures is neither cost effective nor recommended by the international bodies. It becomes more important when the patient and not the state pays for the investigations.

Recommendations

Timely intervention in terms of Endodisinfection and appropriate training of the staff in sterilization and disinfection of the endoscopes as per international guidelines is suggested before it becomes a human rights issue. Universal screening for HBV, HCV and HIV be stopped immediately and only reserved for high risk individuals.

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AUTHOR'S CONTRIBUTION

Following authors have made substantial contributions to the manuscript as under:

- Mehr MT:** Collection and analysing the data, writing the manuscript.
- Uddin S:** Collection of data.
- Iman NU:** Concept and supervision.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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