Leveraging clinical evidence and expertise

Clinical leaflet
Background:

Because of their complex design, duodenoscopes have been long recognized to be difficult to fully disinfect and may play a role in transmission of bacteria between patients. Recent reports of duodenoscope associated carbapenem-resistant enterobacteriaceae (ERCP) transmission have confirmed these suspicions. An outbreak of a multidrug-resistant strain of Escherichia coli was recently reported at our institution. Herein we report the results of our investigation and the process improvements that we deployed in an effort to contain the outbreak.

Methods:

A full investigation into the environment, endoscopists, infection control practices, high-level disinfection process, and endoscopes was undertaken in conjunction with the local county health authority and the Centers for Disease Control and Prevention. Duodenoscopes were cultured and quarantined for 48 hours until negative cultures were obtained. Ergonomic changes were made to the endoscope reprocessing area, duodenoscopes were returned for routine maintenance, and surveillance cultures were obtained from all patients undergoing ERCP.

Results:

Between November 2012 and August 2013, 32 patients were found to harbor one of two clonal strains of multidrug-resistant E. coli, all of whom had undergone ERCP or duodenoscopy. A total of 1149 ERCPs were performed during this time period. Seven patients died within 31 days of the organism being identified in culture, 16 patients died overall by March 2015. The exact contribution of E. coli to death is unclear because most patients had underlying late-stage malignancy or other severe medical comorbidities. No breach in high-level disinfection protocol or infection control practices was identified. The clonal strain of E. coli was identified in culture on four of eight duodenoscopes, three of which required critical repairs despite lack of obvious malfunction. The defect rate in high-level disinfection of duodenoscopes was 2% over a one year period. The implemented quality improvements, subsequent to which 1625 ERCPs have been performed, were successful in halting the outbreak.

Conclusions:

The existing manufacturer-recommended high-level disinfection protocols for duodenoscopes are inadequate. Although the ultimate solution may be a design change to the instrument, the timeline for such a change appears long and potentially difficult to exact. In the interim, a reliable method to ensure that bacterial pathogens are not present on the duodenoscope after high-level disinfection is needed (Gastrointest Endosc 2015;82:477-83).
This publication reports the results of the investigation following an outbreak of a multidrug-resistant strain of E. coli in this institution. Authors took in consideration environment, protocols and equipment in the hospital as possible root causes of the outbreak.

**Key facts**

- 1149 ERCPs performed (November 2012 and August 2013)
- 32 patients infected with multidrug-resistant E. coli
- 7 patients died within 31 days
- 2% defect rate in high-level disinfection of duodenoscopes

**Additional considerations**

32 patients accounts for the 2.7% of the procedures. This can be considered a remarkable number if we correlate it with the early mortality associated with these patients, which in this publication is reported as more than 20%, most likely due to the additional comorbidities characterizing this patient population.

Two percent defect rate in high-level disinfection of duodenoscopes is a rate that has concerned the authors and led them to question policy and process in the institution. Of note is the fact that out of the eight duodenoscopes that were returned to the manufacturer, four required critical repairs despite the devices' lack of functional defects.

**Author remarks**

“Because of design complexities, the duodenoscope has been implicated as a vector for bacterial transmission since its introduction into clinical practice.”

“[...] solution may be a design change to the instrument.”

“Potential solutions include scheduled maintenance after a certain number of uses.”