Efficiency of the Glutaraldehyde Test Strip for Monitoring the Concentration of Glutaraldehyde in Reused Solutions for Disinfecting Endoscopes

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Abstract

Background : Glutaraldehyde has been widely used for low-temperature disinfection of endoscopes. The current practice at Siriraj Hospital is to change the glutaraldehyde solution every 21 days or when the solution appears turbid. The disadvantages of this practice include inadequate disinfection of endoscopes if the concentration of glutaraldehyde in a reused solution is insufficient or wasted if the discarded solution is still active.

Objective : To determine the efficiency of a glutaraldehyde test strip (GTS) in monitoring the amount of glutaraldehyde in a reused solution for disinfecting endoscopes.

Method : Reused glutaraldehyde solutions for disinfecting bronchoscopes, gastroscopes and colonoscopes were tested for the concentration of glutaraldehyde with a GTS thrice weekly for the first week and then every working day up to 56 days. If the GTS indicated a concentration of glutaraldehyde $\geq$ 1.8 per cent after 21 days, 5 ml of the solution was taken to the laboratory to determine its mycobactericidal activity.

Results : All samples of the reused glutaraldehyde solution up to 56 days with a concentration of $\geq$ 1.8 per cent glutaraldehyde on GTS from testings showed mycobactericidal activity. If the glutaraldehyde solution was reused for up to 28, 42 or 56 days, it could save 9,603; 22,813 and 29,415 baht per year respectively for the gastroscopy and colonoscopy units. The corresponding figures were -949; 2,726 and 4,564 baht per year for the bronchoscopy unit. It is estimated that up to 400,000 baht per year could be saved by adopting the strategy of GTS monitoring in all endoscopy units at Siriraj Hospital.

Conclusion : The current strategy of discarding reused glutaraldehyde solution in the gastroscopy, colonoscopy and bronchoscopy units at Siriraj Hospital may be inappropriate since the reused solution is still mycobactericidal for up to 56 days.

Key word : Glutaraldehyde, Glutaraldehyde Test Strip, Endoscopes

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Since the fiberoptic endoscope was introduced in the mid 1950's, there has been increasing use of this diagnostic and therapeutic device. However, without proper decontamination, the potential for transmission of infectious agents to patients undergoing endoscopic procedures has become evident. There have been reports of infections caused by *Pseudomonas aeruginosa*[1], *Proteus* spp[2]. *Serratia marcescens*[3], *Mycobacterium tuberculosis*[4,5] and viral hepatitis[6,7] in patients undergoing endoscopic procedures. The reason for cross infection was inadequate disinfection or sterilization. In order to prevent or reduce the transmission of infectious agents *via* endoscopes, a strict disinfectant or sterilizing process is crucial[8].

Glutaraldehyde is widely used as a high-level disinfectant for medical equipment such as endoscopes. Its advantages include excellent biocidal properties, activity in the presence of organic matter, non-corrosive action on endoscopic equipment and non-coagulation of proteinaceous materials. However, its anti-microbial activity correlates with the concentration of glutaraldehyde which in turn is dependent on its age and the condition in which it is reused, such as dilution and organic stress. Most studies have suggested that 1 per cent glutaraldehyde is the minimal effective concentration (MEC) when used as a high-level disinfectant[9]. A study by Mbithi et al showed that the glutaraldehyde concentration declined from 2.4 per cent to 1.5 per cent after 10 days in manual and automatic baths used for endoscopes[10]. Another study by Leong et al showed the glutaraldehyde concentration declined to below 1 per cent to as low as 0.27 per cent on day 4 of reuse[11]. This information indicates that dilution of the glutaraldehye solution commonly occurred during use. So monitoring of the glutaraldehyde concentration is important to ensure the efficacy of the solution. The glutaraldehyde test strip (GTS) is used for determining whether an effective concentration of glutaraldehyde is present despite repeated use and dilution of the glutaraldehyde solution.

At Siriraj Hospital, glutaraldehyde solution is used as a disinfectant/sterilant solution for medical equipment, especially endoscopes. The amount of glutaraldehyde solution used is 1,660 gallons per year with a total expense greater than 700,000 baht. The current practice at our hospital is to change the glutaraldehyde solution every 21 days or when the solution appears turbid. The disadvantages of this current practice are inadequate disinfection of endoscopes if the concentration of reused glutaraldehyde is below the MEC and wasted if the reused solution is still active. GTS testing has been recently introduced in Siriraj Hospital but there is no information on its efficiency in monitoring the concentration of glutaraldehyde in a reused solution.

The objective of the study was to determine the efficiency of GTS in monitoring the concentration of reused glutaraldehyde solution for bronchoscope, gastroscope and colonoscope disinfection at Siriraj Hospital.

MATERIAL AND METHOD

Glutaraldehyde solution

Cidex, Formula 7 Long-Life Activated Dialdehyde solution was purchased from Johnson & Johnson Medical, Inc. (Thailand) for use in the endoscopy units. The activator provided with the product was added to the glutaraldehyde solution just prior to filling the disinfectant baths at a ratio of 1:1. The concentration of glutaraldehyde in a freshly prepared solution was 2.2-2.6 per cent

Glutaraldehyde test strip

The glutaraldehyde test strip used in the study was the 3983MM cold sterilog glutaraldehyde monitor. It is a semi-quantitative chemical indicator used to determine the MEC of Cidex, Formula 7 Long-Life Activated Dialdehyde solution. The strip is composed of a black outlined paper pad attached to a plastic strip which is used for dipping the pad into the solution. The black outline paper pad is composed of two active ingredients, sodium sulfite (90.5%) and glycine (9.5%). The glutaraldehyde reacts with the sodium sulfite to form a sulfite addition product and sodium hydroxide. The sodium hydroxide then reacts with glycine to form a yellow color. The GTS is dipped into the glutaraldehyde solution and then immediately withdrawn and left for 5 to 8 minutes. Any shade of uniform yellow on the pad indicates a concentration of glutaraldehyde of 1.8 per cent or greater, whereas white remaining on the pad indicates a concentration of glutaraldehyde of less than 1.8 per cent.

Method

Information on the current practice of changing glutaraldehyde solution in the bronchoscopy, gastroscopy, and colonoscopy unit was collected. The annual consumption of glutaraldehyde, the cost of glutaraldehyde solution and the cost of GTS were provided by the Department of Pharmacy. The study

was conducted for 2 cycles of use for each endoscopy unit. During the study period, the concentration of reused glutaraldehyde solution in each bath from each unit was tested with a GTS every Monday, Wednesday and Friday for the first week then every working day for 5 weeks (first cycle) and 7 weeks (second cycle) without giving the results of the GTS testing to the personnel responsible for the endoscopy units. Five millilitres of the glutaraldehyde solution was collected for anti-mycobacterial activity testing on the day on which the reused glutaraldehyde solution was changed but the result on GTS testing showed that the concentration of glutaraldehyde was still above 1.8 per cent and thereafter up to day 56. The personnel in the endoscopy unit were asked to continue using the reused glutaraldehyde solution for disinfecting the endoscopes before re-immersing the endoscopes into newly prepared glutaraldehyde solution after day 21.

Antimycobacterial activity testing

M. tuberculosis (standard strain) was used as the test organism. The inoculum concentration was 3 x 10^7 cells/ml. 100 microlitres of *M. tuberculosis* suspension was inoculated into 900 microlitres of reused glutaraldehyde solution and left for 60 minutes. The mixture was centrifuged at 10,000 rpm for 2 minutes and the supernatant was discarded. The pellet was washed with 1 ml of sterile water and then centrifuged at 10,000 rpm for 2 minutes and the supernatant was discarded. One millilitre of distilled water was added and mixed by vortex. 100 microlitres of the suspension was spread on a Middlebrook 7H10 agar plate and the plate was incubated at 37°C for 3 weeks. *M. tuberculosis* colonies grown on the plate were counted. In order to interprete the culture result from the reused glutaraldehyde solution, the plate subcultured from a control solution without glutaraldehyde had to be positive with a heavy growth of *M. tuberculosis*.

Data analysis

The cost analysis between using GTS to monitor the concentration of reused glutaraldehyde solution and without using GTS was calculated and compared.

RESULTS

The amount of glutaraldehyde solution used was 7 gallons and 2 gallons for each cycle for the gastroscopy/colonoscopy unit and bronchoscopy unit respectively. The duration of each cycle for reusing glutaraldehyde solution was 21 days and 22.5 days for the gastroscopy/colonoscopy unit and bronchoscopy unit respectively. The cost of the solution for each cycle was 3,080 baht and 880 baht for the gastroscopy/colonoscopy unit and bronchoscopy unit respectively. The daily expense was 147 baht and 39 baht for gastroscopy/colonoscopy unit and bronchoscopy unit respectively.

The concentration of the reused glutaraldehyde solutions both in the gastroscopy/colonoscopy unit and bronchoscopy unit was still above the MEC of 1.8 per cent on the day in which the reused solution was changed and was still above MEC of 1.8 per cent on day 42 (1st cycle) and day 56 (2nd cycle). The reused solution was still active against *M. tuberculosis* when it was tested for antimycobacterial activity.

The cost analysis of glutaraldehyde test strip for monitorting the glutaraldehyde concentration on the gastroscopy/colonoscopy units showed that if the glutaraldehyde test strip was not used, the expense for the glutaraldehyde solution per cycle was 3,080; 4,107; 6,160 and 8,213 baht when the duration of use was 21, 28, 42, and 56 days respectively. If the glutaraldehyde test strip was used, the expense for the glutaraldehyde solution and the test strip was 3,288 (3,030 baht for the solution and 208 baht for the GTS); 3,368 (3,080 and 288); 3,528 (3,080 and 448) and 3,688 (3080 and 608) baht per cycle when the the reused duration was 21, 28, 42 and 56 days respectively as shown in Table 1. The annual expense saved would be 9,602; 22,834 and 29,414 baht if the GTS was used to guide the timing of changing the solution and could extend its use from 21 to 28, 42, and 56 days respectively.

The cost analysis of glutaraldehyde test strip for monitorting the glutaraldehyde concentration on the bronchoscopy unit showed that if the glutaraldehyde test strip was not used, the cost of the glutaraldehyde solution for each cycle was 880; 1,095; 1,643 and 2,190 baht when the reused duration was 22.5, 28, 42, and 56 days respectively. If the glutaraldehyde test strip was used, the cost of the glutaraldehyde solution and the test strip was 1,104 (880 baht for the solution and 224 baht for the GTS); 1,168 (880 and 288); 1,328 (880 and 448) and 1,488 (880 and 608) baht when the reused duration was 21, 28, 42 and 56 days respectively as shown in Table 2. The annual expense that would be saved was 2,728 and

Table 1. The cost of glutaraldehyde solution used in the gastroscopy/colonoscopy units when GTS was used and not used.

Duration (days)	Cost of glutaraldehyde solution without using GTS (Baht)	Cost of glutaraldehyde solution when using GTS (Baht)
21	3,080	3,288
28	4,107	3,368
42	6,160	3,528
56	8,213	3,688

Table 2. The cost of glutaraldehyde solution used in the bronchoscopy unit when GTS was used and not used.

Duration (days)	Cost of glutaraldehyde solution without using GTS (Baht)	Cost of glutaraldehyde solution when using GTS (Baht)
22.5	880	1,104
28	1,095	1,168
42	1,643	1,328
56	2,190	1,488

4,563 baht if GTS was used to guide the timing of the glutaraldehyde solution change and could extend its use from 22.5 days to 42 and 56 days respectively.

The overall hospital annual expense for glutaraldehyde solution could be reduced by 148,904; 330,256; and 420,932 baht if the strategy of using GTS to guide the timing of glutaraldehyde solution change and could extend the duration of use from approximately 21 days to 28, 42 and 56 days respectively.

DISCUSSION

The reason the authors selected *M. tuberculosis* as a microorganism for testing the efficacy of disinfectant of reused glutaraldehyde solution was this organism is relatively more resistant to disinfectant than viruses or other bacteria due to the property of its cell wall. So it was assumed that if the reused glutaraldehyde solution could inhibit the growth of *M. tuberculosis*, it should inhibit the growth of other pathogenic microorganisms. The results of this study show that by using GTS to monitor the concentration of glutaraldehyde still present in the solution, the duration of use of the reused solution could be extended up to 56 days. However, for the bronschoscopy unit, if the extended duration of use of reused glutaraldehyde was only 28 days, the annual expense for glutaraldehyde solution using GTS will be higher than without using GTS. But if nosocomial infection control and prevention which is one of the most important indices of the standard care of medical care is of concern, using GTS will enable the use of reused glutaraldehyde solution safely. This study demonstrated that using GTS was efficient in monitoring the concentration glutaraldehyde in the reused solution for disinfecting bronchoscopes, gastroscopes and colonoscopes. However, how frequently the reused glutaraldehyde should be tested needs further investigation. It should be mentioned that the exposure time of *M. tuberculosis* to the reused glutaraldehyde solution in the laboratory in the present study was 60 minutes, therefore it might be necessary to immerse the endoscope for 60 minutes if the reused glutaraldehyde solution is to be used beyond 21 days.

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ความคุ้มค่าของการใช้แผ่นตรวจสอบความเข้มข้นของกลูตาราลดีไฮด์เป็นแนวทางในการเปลี่ยนน้ำยากลูตาราลดีไฮด์สำหรับทำลายเชื้อที่กล้องส่องตรวจภายในทางเดินอาหารและทางเดินอากาศหายใจ

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คณะผู้วิจัยได้ศึกษาความคุ้มค่าของการใช้แผ่นตรวจสอบความเข้มข้นของกลูตาราลดีไฮด์เป็นแนวทางในการเปลี่ยนน้ำยากลูตาราลดีไฮด์สำหรับทำลายเชื้อที่กล้องส่องตรวจภายในทางเดินอาหารและทางเดินอากาศหายใจโดยทดสอบน้ำยากลูตาราลดีไฮด์สำหรับทำลายเชื้อที่กล้องส่องตรวจภายในทางเดินอาหารและทางเดินอากาศหายใจด้วยแผ่นตรวจสอบความเข้มข้นของกลูตาราลดีไฮด์และฤทธิ์ในการทำลายเชื้อวัณโรคเป็นระยะ ๆ นานถึง 56 วันพบว่าน้ำยากลูตาราลดีไฮด์ที่มีความเข้มข้นของกลูตาราลดีไฮด์มากกว่าร้อยละ 1.8 จากการทดสอบด้วยแผ่นตรวจสอบความเข้มข้นของกลูตาราลดีไฮด์ยังมีฤทธิ์ในการทำลายเชื้อวัณโรคได้ หากนำแผ่นตรวจสอบความเข้มข้นของกลูตาราลดีไฮด์มาใช้เป็นแนวทางในการเปลี่ยนน้ำยากลูตาราลดีไฮด์สำหรับทำลายเชื้อที่กล้องส่องตรวจภายในทางเดินอาหารและทางเดินอากาศหายใจน่าจะช่วยเรื่องความปลอดภัยและประหยัดค่าใช้จ่าย

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