



Does the Disinfectant Efficacy of the 2% Gluteraldehyde Solution Change with the Aging of the Solution?

%2 Gluteraldehit Solusyonunun Dezenfektan Etkinliği Solusyonun Yaşlanması ile Değişir Mi?

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Abstract

Purpose: In our study, it was aimed to determine whether the disinfectant efficacy of 2% glutaraldehyde solution changes with the aging of the solution.

Material and Method: In our study, metal obtained from k-wire, plastic obtained from serum sets, and glass balls were used to imitate metal, plastic, and glass materials found in surgical instruments. Each study day, 20 pieces of metal, plastic, and glass materials were contaminated with *Klebsiella Pneumoniae*, *Staphylococcus Aerijs*, *Pseudomonas Aeruginosa*, and *Escherichia Coli* and Maya. The materials were divided into groups of 10. The first group was thrown into the glutaraldehyde solution taken from the aging activated 2% glutaraldehyde solution pool into plastic pet glasses, each piece in separate pet glasses, and kept in the solution for 15 minutes. Afterward, the materials were taken from the cups using different sterile forceps for each piece. The other group was washed with physiological saline solution for 1 minute. After the procedures, it was sent to the microbiology laboratory without waiting and cultured on EMB agar and blood agar.

Results: No growth was detected on the 1st, 14th, and 28th days in all metal, plastic, and glass materials disinfected with 2% alkaline glutaraldehyde solution. In the control groups, growth rates were 53.3%, 50%, and 63.3%, respectively.

Conclusions: If the guidelines and manufacturer's recommendations are followed in the preparation and use of 2% alkaline glutaraldehyde solution, it provides an effective disinfection without being affected by the aging of the solution.

Keywords: Infection, sterilization, disinfection, gluteraldehyde, arthroscopic instrument

Öz

Background: Çalışmamızda %2 gluteraldehit solusyonunun dezenfektan etkinliğinin solusyonun yaşlanması ile değişime uğrayıp uğramadığının tespiti amaçlanmıştır.

Gereç ve Yöntem: Çalışmamızda cerrahi aletlerde bulunan metal, plastik ve cam malzemeleri taklit etmek adına 2 cm uzunluğunda k telinden elde edilen metal, serum setlerinden elde edilen plastik ve cam bilyeler kullanıldı. Her birinden 20'şer adeti solusyonun 1., 14. ve 28. gününde *Klepsiella Pneumoniae*, *Staphylococcus Aerijs*, *Pseudomonas Aeruginosa*, *Escherichia Coli* ve Maya ile kontamine edildi. 10'ar tanesi %2 gluteraldehit solusyon havuzundan plastik pet bardaklara alınan gluteraldehit solusyonu içine her bir parça ayrı pet bardaklarda olacak şekilde atıldı ve 15 dakika süre ile solusyon içerisinde bekletildi. Sonrasında malzemeler bardaklardan her bir parça için ayrı steril forseps kullanılarak alındı. Diğer 10'ar adeti 1 dakika boyunca serum fizyolojik solüsyon ile yıkandı. İşlemler sonrasında bekletilmeden mikrobiyoloji laboratuvarına gönderilerek EMB agar ve kanlı agarda kültürlendi.

Results: %2 alkalen gluteral solüsyonu ile dezenfekte edilen metal, plastik ve cam malzemelerde 1., 14. ve 28. günde üreme tespit edilemedi. Kontrol gruplarında ise sırası ile %53,3, %50 ve %63,3 oranlarında kontaminasyonda kullanılan mikroorganizmalardan bir ve ya birkaçında üreme tespit edildi.

Sonuç: %2 alkalen gluteral solüsyonu hazırlanması ve kullanılmasında kılavuz ve üretici önerilerine dikkat edilmesi halinde solüsyonun yaşlanmasından etkilenmeden aktif olduğu süre boyunca etkin bir dezenfeksiyon sağlar.

Anahtar Kelimeler: Enfeksiyon, sterilizasyon, dezenfeksiyon, gluteraldehit, artroskopik alet



INTRODUCTION

2% glutaraldehyde solution is a disinfectant class chemical. While it does not show any sporicidal activity in acid character, its activated form with alkali gains sporicidal activity.^[1] Since alkaline pH decreases its activity over time by providing polymerization of the glutaraldehyde molecule, 2% glutaraldehyde solution activated with alkali (pH 7.5 - 8.5 increased) is effective for 14-28 days. Here, it is extremely important and necessary to have a color change when the activator is added to the solution so that the activated and unactivated solutions can be easily separated from each other. In addition, chemical test strips are required to check for the decreasing glutaraldehyde concentration at 14-28 days. Although the glutaraldehyde solution maintains its activity in the presence of organic matter, strips are also required here, as organic substances mixed in the solutions in which the instruments are immersed can reduce the glutaraldehyde concentration.

2% activated alkaline glutaraldehyde is widely used for disinfection of heat-sensitive equipment, especially flexible fiberoptic endoscopes. It is effective against a wide variety of pathogens and is not corrosive.^[2,3] Although this frequently used disinfectant is effective, there are studies in the literature indicating that infection develops after arthroscopic procedures using arthroscopic instruments disinfected with 2% glutaraldehyde.^[4,5] In addition, evidence has been presented in the last decade that reprocessing endoscopic instruments is generally not effective. In studies, microbial growth was detected between 16% and 71% in samples taken from flexible endoscopes disinfected with high-level disinfectants.^[6-8]

Alkaline pH decreases its effectiveness over time by providing the polymerization of the glutaraldehyde molecule. In our study, it was aimed to determine whether the microbiological disinfectant effectiveness of 2% glutaraldehyde solution, which enters the aging process after the activator is added, will change over time.

MATERIAL AND METHOD

The study was designed as a prospective, experimental study after obtaining approval from the local ethics committee with registration number 20-KAEK-156. In our hospital, glutaraldehyde solution is used in arthroscopic instrument disinfection. This solution contains 2% glutaraldehyde, anticorrosive materials, auxiliary materials, and de-ionized water. After the solution is prepared in containers large enough to fit the surgical instruments comfortably, its effectiveness is evaluated daily with test strips and used for 28 days. The solutions that are found to have ceased efficacy with test strips and/or whose color change is detected in the solution are discontinued from use.

In the study, the microbiological disinfectant efficacy of 2% glutaraldehyde solution, which is made alkaline after adding the activator on the 1st, 14th, and 28th days was evaluated. To imitate metal, plastic, and glass materials found in surgical

instruments, 2 cm metal obtained from k-wire, 2 cm plastic obtained from serum sets, and glass balls were used. Each study day, 20 pieces of metal, plastic, and glass materials were contaminated with *Klebsiella Pneumoniae* (*K. pneumoniae*), *Staphylococcus Aereus* (*S. aureus*), *Pseudomonas Aeruginosa* (*P. aeruginosa*), and *Escherichia Coli* (*E. coli*), and Yeast which there are grown on Blood agar and EMB agar. After the materials to be contaminated were placed in the petri dish and the petri lid was closed, they were shaken until they were contaminated, and the contamination process was ensured. After contamination, 10 pieces of metal, plastic, and glass materials were thrown into the glutaraldehyde solution taken from the glutaraldehyde solution pool in separate containers, and kept in the solution for 15 minutes. The materials were then taken from the containers using separate sterile forceps for each. The other 10 pieces of metal, plastic, and glassware were washed with saline solution for 1 minute. The materials were immediately sent to the microbiology laboratory after the procedure. The samples taken for evaluation were planted in 5% sheep blood agar (RDS, Turkey), Eosin Methylene Blue agar (RDS, Turkey), and chocolate agar (RDS, Turkey). It was incubated in the oven at 35-37°C for 24-48 hours. Strains were identified by catalase test and tube coagulase test in gram positive bacteria, oxidase test and biochemical tests in gram negative bacteria, and gram staining in yeasts. In addition, it was confirmed that the 2% glutaraldehyde solution pool was active with the test strip on each study day. In addition, patients who underwent arthroscopic surgery during this period were followed for postoperative infection for 6 months. Parts treated with 2% glutaraldehyde solution constituted the working group, while parts washed with SF made up the control group.

RESULTS

In our study where we analyzed whether the disinfection efficiency of 2% Glutaraldehyde changes with the aging of the solution;

1. No growth was detected in any material in the study group on day 1 of the solution. In the control group, reproduction was detected in 16 (53.3%).
2. There was no growth in the study group on the 14th day of the solution as on the 1st day. Reproduction was detected in 15 (50%) of the control group.
3. While there was no growth in the study group on the 28th day of the solution as in the 1st and 14th days, 19 (63.3%) growth was detected in the control group.

Microorganisms grown in the control group on days 1, 14 and 28 included one or more of the microorganisms used in contamination.

During this period, no infection was observed in any of the 45 arthroscopic surgical interventions (17 shoulders, 22 knees, 5 ankles, and 1 elbow) performed with arthroscopic materials disinfected using 2% glutaraldehyde solution during the 6-month follow-up.

DISCUSSION

Arthroscopic surgery has become a frequently performed orthopedic surgical procedure due to the increasing frequency and the widening of the range of indications. With this increase, it may not be economically feasible to have sufficient surgical equipment to perform more than one arthroscopic procedure on the same day. Arthroscopes that enter sterile body areas should ideally be sterilized before use. Steam autoclaving is recommended for this job.^[9] Repeated steam autoclaving can shorten the lifetime of arthroscopes and laryngoscopes by causing the adhesives between the main lenses to deteriorate and the light intensity to decrease.^[9,10] Gas sterilization with ethylene oxide is effective and safe, but has the disadvantage that it is not available in every institution; It is also a very time-consuming process as it requires four to twelve hours for sterilization and aeration. In studies comparing ethylene oxide sterilization and high-level disinfection of glutaraldehyde, no difference was found between infection rates.^[11]

2% alkaline glutaraldehyde has a wide spectrum of action against bacteria and their spores, fungi, and virus.^[12] Although sterilization is preferred for arthroscopic instruments, when the sterilization of arthroscopes and laparoscopes is examined; While studies are stating that 2% alkaline glutaraldehyde is an acceptable decontamination method.^[5,13,14] studies are stating that a sufficient decrease in the number of coloni forming units(CFU) could not be detected after high-level disinfection with glutaraldehyde in the opposite direction.^[15,16] Over the past 10 years, evidence has been presented that reprocessing for endoscopes is generally not effective. Studies have documented microbial growth rates between 16% and 71% in samples taken from flexible endoscopes disinfected with high-level disinfectants^[6-8] Reprocessing failures can have serious consequences for patients. Post-endoscopic infections can be common (> 3%) even if patients take prophylactic antimicrobials.^[6,17] In our study, the absence of culture growth in plastic, metal, and glass materials decontaminated with 2% glutaraldehyde on the 1st, 14th, and 28th days and the absence of infection after arthroscopic surgeries supports the studies stating that 2% glutaraldehyde is effective in decontamination, but it differs from studies in the opposite direction.

This difference in the literature, between studies;

1. Human factors that contribute to non-compliance with the guidelines, standards, and manufacturer's instructions for use,
2. Clinical use of visibly damaged endoscopes,
3. From the use of products that may interfere with rework (simethicone, lubricants, and tissue glue)
4. After manual cleaning, the presence of residual dirt,
5. Rinsing water quality problems,
6. Moisture retained in completely reprocessed endoscopes,
7. Differences between rigid and flexible endoscopes

8. It has been stated that it is caused by the differences in the anatomical region and the environment in which the medical procedure is performed.^[18-21]

While baths containing 2% activated alkali glutaraldehyde has a minimum shelf life of 14 days, new glutaraldehyde formulations produced in the last 30 years have overcome the problem of rapid activity loss and excellent microbicidal activity has been achieved for 28-30 days.^[22,23] With the aging of the alkaline glutaraldehyde solution, its concentration and pH decrease, and the protein concentration increases.^[24,25] It has been stated that more dilution occurs in automatic glutaraldehyde baths compared to manual baths.^[24,25] Accordingly, studies are stating that its effect on microbiological activity will be adversely affected.^[14,26,27] In addition, it has been stated that the number of devices subjected to a chemical under re-use conditions may cause a loss of efficiency.^[24,25] In the literature, it has been stated that 1% to 1.5% glutaraldehyde shows a minimum effective concentration when used as a high-level disinfectant.^[28,29] Our study data show that the reuse of 2% glutaraldehyde is effective for 28 days. In this event; The fact that we are doing the disinfection process in operating room conditions and with operating room personnel, using a manual glutaraldehyde bath, disinfection cycle, and the amount of disinfected equipment may affect.

Postoperative infection can be devastating for patients after clean joint surgery.^[30] A retrospective study involving 12,505 arthroscopic procedures found an infection rate of 0.04% (five infections) when arthroscopes were immersed in 2% glutaraldehyde for 15-20 minutes. In four patients, infection developed after the combination of open surgery after arthroscopy.^[5] In another arthroscopy study, infection developed in three patients following 151 arthroscopies over a period of 2 months. After the improvement of environmental conditions, it was stated that there was no infection in 222 arthroscopies^[4] In those studies, the source of infection was expressed as skin flora and contamination from the environmental environment. In our study, although the number of patients who were operated on with decontaminated arthroscopic instruments was low, the absence of a patient who developed an infection clinically supports the fact that effective disinfection was obtained by keeping the arthroscopic surgical instruments in 2% glutaraldehyde solution for 15 minutes. Although high infection rates.^[6-8] are indicated in samples taken after disinfection for re-use for endoscopes and bronchoscopes, low infection rates after arthroscopic surgeries; may be due to multifactorial reasons such as the use of short, smooth-surfaced, jointless rigid arthroscopes, the procedures being performed in operating room conditions, compliance with the rules in disinfectant preparation and follow-up, and more attention to the disinfection process, the use of positive pressure washing solutions to expand the working area in the joint, and working in sterile anatomical areas.

CONCLUSIONS

Arthroscopes, laparoscopes, etc. surgical equipment that penetrates sterile tissue, such as, should be sterilized before each use; If this is not possible, at least a high level of disinfection is required. 2% alkaline glutaraldehyde solution; It shows an effective disinfectant activity for 28 days if it is observed in the preparation and disinfection process following the guidelines and the manufacturer's recommendations, paying attention to the maintenance of the surgical equipment and cleaning before and after the operation, taking care of environmental factors such as temperature and humidity, and evaluating the daily activity of the solution with test strips.

While evaluating the disinfectant activity with the aging of 2% alkaline glutaraldehyde solution, the fact that dilution amount, pH changes, and protein concentration values that may affect the disinfectant efficacy with aging were not examined constitute the negative aspects of our study.

ETHICAL DECLARATIONS

Ethics Committee Approval: The study after obtaining approval from the local ethics committee with registration number 20-KAEK-156.

Informed Consent: All patients signed the free and informed consent form.

Referee Evaluation Process: Externally peer-reviewed.

Conflict of Interest Statement: The authors have no conflicts of interest to declare.

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