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Research Article

A Comparative Study of Efficacy of Disinfectants Used for Flexible Endoscope: Glutaraldehyde versus Ortho-Phthalaldehyde

S.P. Venkatesh[1], S. Kothandapani[2], R. Marudavanan[3], S. Ponraj[4]
[1]Assistant Professor, Department of Surgery, Sri Manakula Vinayagar Medical College and Hospital, Kalitheerthalkuppam, Puducherry – 605107, India
[2]Professor, Department of Surgery, Sri Manakula Vinayagar Medical College and Hospital, Kalitheerthalkuppam, Puducherry – 605107, India
[3]Professor, Department of Surgery, Sri Manakula Vinayagar Medical College and Hospital, Kalitheerthalkuppam, Puducherry – 605107, India
[4]MBBS Student, Sri Manakula Vinayagar Medical College and Hospital, Kalitheerthalkuppam, Puducherry – 605107, India

***Corresponding author**
S.P. Venkatesh
Email: drvenkateshsp@gmail.com

Abstract: Endoscopes have been used widely for the diagnosis and therapy of many surgical disorders. Endoscopes are classified as semicritical item and thus though sterilisation is ideal, high-level disinfection is sufficient enough and is the current reprocessing standard for flexible endoscope after each patient use. Glutaraldehyde (2%) has been used widely as a high level disinfectant for over 30 years now because of its favourable materials compatibility and cheaper cost but its immersion time is longer. The later arrival 0.55% Ortho-phthalaldehyde (OPA) is promising because of its excellent bactericidal activity, wide range of material compatibility and lesser immersion time but is not widely used mainly because of its cost factor. Another advantage of using OPA is that it is effective against Glutaraldehyde resistant mycobacteria. The study is a prospective randomised controlled trial comparing cost effectiveness, safety and handling issues of 2% Glutaraldehyde and 0.55% Ortho-phthalaldehyde for disinfecting endoscope in our endoscopy unit. It was observed that Ortho-phthalaldehyde was found to be more cost effective than the former (profit of Rs. 40000 as compared to Rs.22950 during a study period of 20 days for each). It is very doctor friendly as more number of patients could undergo endoscopy in a day (maximum 5 when compared to only 3 maximum with the former), needed only 10 min for disinfection (compared to 20 min), does not need any activation before use hence reducing waiting time between two patients especially in a busy unit with only one endoscope. The microbiological safety is also better with the latter agent (high level disinfection rate reaching almost 100%) obviating the need for replacing the long used Glutaraldehyde.
Keywords: Endoscope; disinfectants; Glutaraldehyde; Ortho-phthalaldehyde

INTRODUCTION

Flexible endoscopes have been used widely for the diagnosis and therapy of many surgical disorders and are contaminated routinely by microorganisms during clinical use on the patients [1]. Since endoscopes are reusable apparatus, cleaning and disinfection are very important to minimize the spread of infection through endoscopes. Endoscopes are classified as semicritical item [2] and thus though sterilisation is ideal, high-level disinfection is sufficient enough and is the current reprocessing standard for flexible endoscope after each patient use [1].

Sterilization refers to a process which results in the complete elimination or destruction of all forms of microbial life whereas High-level disinfection refers to the destruction of all microorganisms with the exception of high levels of bacterial spores [3]. The characteristics of an ideal chemical sterilant used as a high-level disinfectant should include broad antimicrobial spectrum, rapid activity, material compatibility, lack of toxicity to humans and the environment, odourless, non staining, unrestricted disposal, prolonged reuse life and shelf life, easy to use, resistant to organic material, ability to be monitored for concentration and cost effective [1].

High level disinfection of flexible endoscope is very necessary between two patients use and many agents are available for the same of which 2% glutaraldehyde is widely used because it is non corrosive, has good microbiological safety and cheaper in cost [4]. Most endoscopy clinics use 2% glutaraldehyde as a high-level disinfectant for

reprocessing flexible endoscopes. However, even with contact times greater than 30 minutes, survival of organisms has been documented [5]. Its relatively slow microbicidal activity limits the number of patients who can undergo endoscopy on a single day in many hospitals especially which have only one endoscope (long immersion time of 20 – 45 min) and also the occupational health hazard like irritating odour, skin and respiratory irritation remain a concern [6]. In addition potential mutagenic and carcinogenic effects have been reported [7] and such a risk to personnel and the increasing frequency of GTA-resistant Atypical mycobacteria [8] obviates the need for a better disinfecting agent.

The other promising disinfectant 0.55% Ortho-phthalaldehyde (OPA) has lesser immersion time (5 to 10 min) and lesser handling issues but is not widely used mainly because of its cost factor (Rs. 3000 for OPA 5 litres compared with Rs.775 for Glutaraldehyde 5 litres). Manufacturer's data show that OPA will last longer before reaching its minimum effective concentration limit (about 82 cycles) compared with glutaraldehyde (after 40 cycles) [9]. Another advantage of using OPA is that it is effective against Glutaraldehyde resistant mycobacteria, especially M. bovis [10]. This higher cost would be offset, however, by additional time savings resulting from the fact that compared with glutaraldehyde, ortho-phthalaldehyde is faster-acting and a mixing and activation step is not required. In addition, testing prior to each cycle verified that despite heavy use, ortho-phthalaldehyde solution remained efficacious, lasting through an average of 80 cycles, whereas glutaraldehyde only lasts for an average of 40 cycles [11]. If OPA is used, more number of patients can undergo endoscopy in a single day and in a busy endoscopy unit there is a risk of human impatience to wait for the full immersion period of 20 min for Glutaraldehyde which is eliminated in case of OPA, thus safer too.

A study by Cooke *et al*. showed that the cost input to change from Glutarladehyde to Ortho-phthalaldehyde was significantly higher and also the staining problem of the latter was a big concern which was not seen with the former [12].

The present study was designed to compare the cost effectiveness of Glutaraldehyde and Ortho-phthalaldehyde used for disinfecting endoscopes, to derive the practical re-usage period, to find out the microbiological safety of both the agents and to compare the handling issues of both the agents.

MATERIALS AND METHODS

The study is a randomised controlled trial comparing 2% Glutaraldehyde and 0.55% Ortho-phthalaldehyde for disinfecting endoscope in our endoscopy unit in the department of Surgery, Sri Manakula Vinayagar Medical College, Puducherry.

A total of 40 days was taken for the study using the agents on alternate days. So both agents were used for 20 days each alternatively. A swab culture was taken from the tip of the endoscope after using on a patient. Then the scope was cleaned externally with running water, internally the channels were flushed and then the scope was immersed fully in the disinfectant agent for the prescribed time of 20 minutes for Glutaraldehyde and 10 minutes for Ortho-phthalaldehyde. After the immersion time period the scope was dried, again swab culture taken from the same tip and then used for the next patient. The disinfection procedure was done at room temperature itself as recommended by the manufacturers of both agents.

The disinfectant agents were reused (i.e., on alternate days as per the study) till they retain the minimum effective concentration which was revealed by the colour change as suggested by the manufacturers strips after which they were discarded and new pack sought.

The handling issues such as staining and irritation to skin, eyes and respiratory tract for both the agents was assessed by enquiring about the difficulties and exposure reactions experienced by the endoscopist and the staff nurse.

Following variables were compared:

- Number of patients who can undergo endoscopy per day for both the agents
- Cost of the disinfectant for the usage of 20 days
- Cost effectiveness (Total income - cost of the disinfectant used)
- Microbiological safety – Culture positivity after disinfection
- Re-usage period
- Handling issues

RESULTS

It was observed that during the study period, the number of patients who underwent endoscopy on each day differed from 2 to 3 cases in case of Glutaraldehyde being used as the disinfectant (Table 1). In the study period of 20 days of using this agent, the endoscopy could be recycled and used on 49 patients totally giving the average number of times the endoscope used in this period 49/20 = 2.45.

The common organisms which were grown in the culture obtained from the tip of the endoscope before and after the disinfection process was as given in the table. It was found that on 2 incidents Pseudomonas aeroginosa remained resistant to the action of the Glutaraldehyde giving the culture positivity of 2/49 = 4.08%.

Table 1: Glutaraldehyde – culture reports

Day	No. of Cases	Culture	
		Before Disinfectant	**After Disinfectant**
1.	2	E.coli, Klebsiella, Pseudomonas	Pseudomonas aeroginosa
2.	3	Klebsiella,E.coli	N
3.	2	E.coli	N
4.	2	Staph. aureus,E.coli	N
5.	3	E.coli, Pseudomonas	N
6.	3	E.coli	N
7.	2	Pseudomonas ,E.coli, Klebsiella	N
8.	3	Staph.aureus	N
9.	2	E.coli	N
10.	2	Staph. aureus	N
11.	3	Staph.aureus, E.coli,	N
12.	2	E.coli, Pseudomonas, Staph.aureus,	Pseudomonas aeroginosa
13.	3	Kliebsiella, Staph.aureus, E.coli	N
14.	2	Pseudomonas aeroginosa	N
15.	3	Staph.aureus, E.coli	N
16.	2	Staph.aureus, E.coli	N
17.	2	Pseudomonas	N
18.	3	E.coli	N
19.	3	E.coli	N
20.	2	E.coli	N

20 days 49 cases

N – Negative, Average no. of cases per day = 2.45, Culture positivity = 4.08%

While using Ortho-phthalaldehyde it was observed that during the study period, the number of patients who underwent endoscopy on each day differed from 3 to 5 cases (Table 2). In the study period of 20 days of using this agent, the endoscopy could be recycled and used on 86 patients totally giving the average number of times the endoscope used in this period 86/20 = 4.30.

The common organisms which were grown in the culture obtained from the tip of the endoscope before and after the disinfection process was as given in the table and it was found that the post disinfectant culture was negative on all occasions and hence the culture positivity was 0%.

Table 2: Ortho-phthalaldehyde – culture reports

Day	No. of Cases	Culture	
		Before Disinfectant	**After Disinfectant**
1.	3	Staph.aureus, E.coli	N
2.	5	Staph.aureus	N
3.	3	E.coli, Pseudomonas	N
4.	5	E.coli, Klebsiella	N
5.	5	E.coli	N
6.	4	E.coli ,Staph.aureus,	N
7.	5	Staph. aureus, E.coli	N
8.	5	E.coli	N
9.	4	E.coli, Klebsiella , Salmonella	N
10.	5	Klebsiella, Pseudomonas	N
11.	3	Pseudomonas	N
12.	4	Pseudomonas, Candida	N
13.	5	Pseudomonas, E.coli	N
14.	4	Pseudomonas, E.coli	N
15.	5	Klebsiella, E.coli	N
16.	5	Candida, E.coli	N
17.	4	Pseudomonas, E.coli	N
18.	3	Klebsiella, E.coli, Pseudomonas	N
19.	4	Candida, H.pylori	N
20.	5	E.coli, Pseudomonas	N

20 days 86 cases

N – Negative, Average no. of cases per day = 4.30, Culture positivity = 0%

While calculating the cost effectiveness, it was better calculated as a profit for the hospital i.e Income – cost input for the two agents (Table 3). As mentioned in the table, in the study period of 20 days of Glutaraldehyde 2 bottles were used compared to only 1 bottle of Ortho-phthalaldehyde. This was because the reusage period was only 15 days (38 cases) for Glutaraldehyde compared to 20 days (all 86 cases) for Ortho-phthalaldehyde. Hence the cost of the agents used was Rs.1550 (755 * 2) for Glutaraldehyde and Rs. 3000 for the single bottle of Ortho-pthalaldehyde. But the profit for the hospital in the 20 days period of Glutaraldehyde was only Rs. 22950 (49*Rs.500 – 1550) while it was higher Rs. 40000 (86*Rs.500 – 3000) for Ortho-phthalaldehyde which is really a significant difference factor for consideration.

Table 3: Comparative variables

Sl. No.	Parameters	Glutaraldehyde	Ortho-pthalaldehyde
a.	Practical Re-usage Period	15 days	20 days
b.	No. of bottles	2	1
c.	Total No. of Patients	49	86
d.	Cost	Rs. 1550	Rs. 3000
e.	Total Income (c*500)	Rs. 24500	Rs. 43000
f.	Profit (e-d)	Rs. 22950	Rs. 40000

On assessing the handling issues it was found that there were no significant differences between the two agents since both caused irritation to eyes and respiratory tract except that with Ortho-phthalaldehyde there is a problem of staining the clothes.

DISCUSSION

Our study was basically intended to find out the cost effectiveness of the two disinfectants used for flexible endoscope in a busy endoscopy unit. Our results showed that when Ortho-phthalaldehyde was used for disinfection, the number of patients who can undergo the procedure on a particular day was more than compared with that of the Glutaraldehyde (the average no. of patients / day 4.30 versus 2.45). This was mainly because of the fact that the standard immersion period for the former agent is only 10 minutes when compared to 20 minutes for the latter agent (almost twice the time) and also the former agent does not need any mixing and activation unlike the latter before use. So the appointments for the endoscopy could be given to more patients on a day when the former agent was used decreasing the waiting period for the patients. Indirectly the time the Endoscopist had to wait before proceeding to the next patient was very less when the former was used which is a matter of concern in a busy unit with only one endoscope available.

During the study period for Ortho-phthalaldehyde, it was found that the agent retained the minimum effective concentration as indicated by the manufacturer's strip throughout the whole period of 20 days and hence one bottle was sufficient (Input Cost Rs.3000) while for Glutaraldehye, it was found that after 15 days usage of around 38 cases, the agent had to be replaced as suggested by the manufacturer's strip indicator of colour change for minimum effective concentration. So two bottles had to be used and hence the cost input of Rs. 1550 (2*Rs.775) but it has to be mentioned here that the second bottle could have been used for some more days after the study period was over, which should not make any big difference.

While assessing the profit when Ortho-phthalaldehyde was used, it was observed that the income after subtracting the cost input for the 20 days study period was very high (Rs.40000 versus Rs.22950). This major difference is of course because of the fact that more number of cases can be done during the 20 days period which should enlighten us that Glutaraldehyde need not be used as widely as now, only because it is cheaper, in the long run it is not going to yield like the other.

On assessing the microbiological safety which is of vital importance it was found that Ortho-phthalaldehyde achieved 0% culture positivity after disinfection or rather 100% high level disinfection in our study when compared to 4.08% culture positivity for Glutaraldehyde. This is a bigger advantage when former was used especially against Pseudomonas. It has to be mentioned here that atypical mycobacterial culture was not done because it had been well documented in previous studies that Glutarladehyde is not effective against those organisms while Ortho-phthalaldehyde is effective.

As mentioned in the results, the handling issues were equal for both the agents and the staining problem of Ortho-phthalaldehyde could be avoided by careful handling.

CONCLUSION

Ortho-phthalaldehyde (0.55%) is a very good alternative to the widely used Glutaraldehyde (2%) for high level disinfection of flexible endoscope in terms of cost effectiveness as well as microbiological safety.

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REFERENCES

1. Rutala WA, Weber DJ; Disinfection of endoscopes: review of new chemical sterilants used for high-level disinfection. Infect Control Hosp Epidemiol., 1999; 20(1): 69-76.
2. Beilenhoff U, Neumann CS, Rey JF, Biering H, Blum R, Cimbro M *et al.*; ESGE-ESGENA Guideline: cleaning and disinfection in gastrointestinal endoscopy. Endoscopy. 2008; 40(11): 939-957.
3. Rutala WA; APIC guideline for selection and use of disinfectants. 1994, 1995, and 1996 APIC Guidelines Committee. Association for Professionals in Infection Control and Epidemiology, Inc.. Am J Infect Control, 1996; 24(4): 313-342.
4. Omidbakhsh N; A new peroxide-based flexible endoscope-compatible high-level disinfectant. Am J Infect Control, 2006; 34(9): 571-577.
5. Vesley D, Melson J, Stanley P; Microbial bioburden in endoscope reprocessing and an in-use evaluation of the high-level disinfection capabilities of Cidex PA. Gastroenterol Nurs., 1999; 22(2): 63-68.
6. Gray J; Finding an alternative endoscope disinfectant to glutaraldehyde. Prof Nurse., 2005; 20(6): 50-51.
7. Hugo WB, Russell AD; Types of antimicrobial agents. In Russell AD, Hugo WB, Ayliffe GAJ editors; Principles and Practice of Disinfection, Preservation and Sterilization. 3rd edition, Oxford: Blackwell Science, 1999.
8. Griffiths PA, Babb JR, Bradley CR, Fraise AP; Glutaraldehyde-resistant Mycobacterium chelonae from endoscope washer disinfectors. J Appl Microbiol., 1998; 82(4): 519-526.
9. Walsh SE, Maillard JY, Russell AD; Ortho-phthalaldehyde: a possible alternative to glutaraldehyde for high level disinfection. J Appl Microbiol., 1999; 86(6): 1039-1046.
10. Rutala WA, Weber DJ; New disinfection and sterilization methods. Emerg Infect Dis., 2001; 7(2): 348-353.
11. Hession SM; Endoscope disinfection by ortho-phthalaldehyde in a clinical setting: an evaluation of reprocessing time and costs compared with glutaraldehyde. Gastroenterol Nurs., 2003; 26(3): 110-114.
12. Cooke RP, Goddard SV, Whymant-Morris A, Sherwood J, Chatterly R; An evaluation of Cidex OPA (0.55% ortho-phthalaldehyde) as an alternative to 2% glutaraldehyde for high-level disinfection of endoscopes. J Hosp Infect., 2003; 54(3): 226-231.