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Review Article

Efficacy and effectiveness of alcohol in the disinfection of semi-critical materials: a systematic review

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Objective: to assess the efficacy and the effectiveness of 60-80% alcohol (v/v) in the disinfection of semi-critical materials which were either previously cleaned or not. Method: studies obtained from BIREME, IBECS, MEDLINE, ScIELO, PubMed, Ask Medline web portals, and references from other studies. Criteria were created to assess the methodological quality of articles. Out of the 906 studies found, 14 have been included. Results: after materials were disinfected with alcohol, microorganisms were detected in 104/282 (36.9%) effectiveness tests and in 23/92 (25.0%) efficacy tests that were conducted. In the field studies, disinfection was not achieved for 74/218 (33.9%) of the products that were submitted to previous cleaning and for 30/64 (46.9%) of the ones which were not submitted to previous cleaning. In the experimental studies, alcohol disinfection was not efficacy in 11/30 (36.7%) and 12/62 (19.4%) of products, respectively. The studies were not found to have followed standardized methods. Conclusion: disinfection of semi-critical products with alcohol 70% - or in an approximate concentration - cannot be recommended to all health care products in an unrestricted way. However, according to the type of semi-critical product, disinfection can be attained with or without previous cleaning.

Descriptors: Ethanol; Disinfection; Decontamination; Efficacy; Effectiveness.

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Introduction

Health care products which are manufactured from noble raw materials such as metals, silicone, fabrics, and rubbers are used countless times among patients in health care services. These products need to be decontaminated with each use, as a way to avoid the risk of cross-contamination by microorganisms.

Choosing a decontamination method depends on the specific risk from a product to cause infections. The current adopted theoretical framework is, generally speaking, the same that was proposed in 1958, when minimum safety procedures were determined to be adopted according to the various risk degrees; that is, sterilization for critical materials - the ones which get in contact with sterile human tissues; the high-level disinfection; and, if possible, sterilization for semi-critical materials - the ones which get in touch with nonintact skin or mucous membranes; and cleaning that is followed by intermediate or low-level disinfection as a standard procedure for non-critical materials - the ones which contact intact skin or which do not get in contact with patients[1]. At the time, the authors have not emphasized the previous need of cleaning as an essential procedure for processing materials to be disinfected or sterilized, which is nowadays adopted as a strong recommendation.

In the health care practice, semi-critical materials such as blades and handles from laryngoscopes, nasovideoscopes, and high-rotation dental drills are disinfected with alcohol 70% (w/v), and intermediate-level disinfectant, after being either previously cleaned or not[2], which is justified by its practicality, accessibility, and low cost.

This investigation was developed in order to answer the question regarding the effectiveness or efficacy of disinfection of semi-critical materials with alcohol, in concentrations which are close to 70% (w/v), with and without previous cleaning. This study is characterized as a systematic bibliographical review of the scientific literature.

The questions which drove this systematic review were: "Is the practice of disinfection semi-critical material, non-previously cleaned with alcohol, in an approximate concentration of 70% (w/v), safe to eliminate expected microorganisms?" "When such products are previously cleaned before being disinfected, does that result in effectiveness and/or efficacy differences?"

Thus, the objective of this review was to assess the efficacy and the effectiveness of alcohol - in an approximate concentration of 70% (w/v) - in the disinfection of semi-critical materials which were either previously cleaned or not, as shown by the scientific literature.

Methods

Evidence-based practice (EBP) is defined by the Evidence Based Medicine Work Group (Canada) as the process of systematically finding, evaluating, and using findings from investigations as bases for clinical decisions[3] and it sees systematic reviews as important resources, in which the information related to a certain problem are collected, categorized, evaluated, and synthesized[4].

This study is a systematic review of the literature, and it is based on basic research, in order to answer the study questions.

The studies were obtained from public domain websites: BIREME (Latin American and Caribbean Center on Health Sciences Information) web portal, which allows searching in databases and web portals on the Latin American and Caribbean literature on health sciences (LILACS), *Índice Bibliográfico Español en Ciencias de la Salud (*IBECS), National Library of Medicine/NLM (MEDLINE), The Cochrane Library, and Scientific Electronic Library Online (SciELO); National Library of Medicine/NLM (PubMed); and Ask Medline. Publications mentioned as references in selected articles were included in this review, provided they met the inclusion criteria.

The health care keywords that were used in the search, with the aid of boolean connectors, were the following: cleaning *OR* disinfection *OR* decontamination AND ethanol *OR* 1-propanol *OR* 2-propanol. The search in English language databases was conducted with the following *Medical Subject Heading* (MeSH) terms: *cleaning* OR *disinfection* OR *decontamination* AND *alcohol* OR *n-propanol* OR *1-propanol* OR *2-propanol* OR *isopropanol* OR *ethanol*. The following question was asked on Ask Medline: *Is the practice of disinfection semi-critical materials with alcohol 70% (w/v) without previous cleaning safe? Is there a difference when it is preceded by cleaning?*

The inclusion criteria for the studies were: primary studies or systematic reviews which discussed the efficacy (in a laboratory) or the effectiveness (in the field) of disinfection semi-critical health care products with alcohol in an approximate concentration of 70% (w/v) - 60% to 80% - without them being previously cleaned,

which resulted in the elimination of microorganisms as expected in the high-level disinfection. Studies needed to have been published until July 2013, and all languages were accepted.

When the aim is to evaluate the effectiveness and/or efficacy of disinfection semi-critical health care products, two parameters may be used in order to define whether high-level disinfection was achieved: 1) elimination of vegetative microorganisms, viruses, fungi, mycobacteria, with the exception of some bacterial spores[1] and 2) microbial load reduction by 6 logarithms[5]. The first parameter was chosen in this study, as not all authors in this review used positive control samples (baseline sampling), neither have they measured initial and final microbial loads before and after health care products were disinfected, so they could evaluate the efficacy and/or effectiveness of alcohol disinfection through log reduction.

The exclusion criteria were: reflection articles, narrative reviews, articles in which alcohol was not the main active disinfection ingredient, and articles which did not discuss the disinfection of semi-critical materials.

The studies were analyzed by four researchers, three of whom specialists in the field and in the investigation methods. The analysis and selection of studies were conducted in three stages. In the first one, which was conducted by a single investigator, the studies were analyzed and pre-selected, according to the inclusion and exclusion criteria figuring in their abstracts - when they did not have abstracts, the full articles were analyzed. After the pre-selection, the studies were analyzed with a data collection instrument that was based on the model from Mendonça, 2008*, including: type of investigation, objectives, sampling, method, consequences, results, and conclusion. The third stage comprised the evaluation of the studies by the four investigators in an independent way, in order to collect data which were specific to the objectives of this systematic review, which led to the selection of the articles which were used in this research. Meetings were conducted for researchers to discuss and achieve consensus on the studies, and on their inclusion or exclusion. In the absence of guidelines to analyze how consistent experimental or field studies were, criteria were created to assess the methodological quality of articles (Figure 1).

A total of 906 studies were found in the databases after keyword-related searches were done. Of those, 11 met the inclusion criteria. Besides those, 3 articles were included based on excerpts from their bibliographical references in surveyed studies. The reasons for the exclusion of 896 studies are found in Table 1.

Evaluation criteria
Active ingredient in the alcohol
1. Description of alcohol type (ethanol, isopropyl, etc.)
2. Description of alcohol concentration
Method for alcohol application
3. Description of the length of time for contact of the alcohol with the health care product - minimum of 30” through rubbing or immersion
4. Description regarding whether the alcoholic solution was discarded with each use, in the case of disinfection through immersion
5. Description of the type of material used for rubbing alcohol on the health care product (fabrics, compresses, gauze, among others), when rubbing methods are used
Collection technique for the microbiological sample
6. Alcohol must be allowed to completely evaporate before the microbiological material can be collected. Alternatively, a neutralizing agent can be used in the culture medium
7. Use of a validated method, or alternatively validating the method of maximum microorganism loading for the collection of the biological sample
8. Description of the surface area for the health care product in which the sample was collected. Ideally, the sample must be collected from all surfaces of the product
9. Description of the use of aseptic technique during the microbiological sample collection
10. Description of the type of material used for recovering microorganisms from disinfected products (gauze, swab, direct inoculation)
Sample characterization
11. Use of sonication and/or agitation, or yet another method, which is validated for purposes regarding satisfactory releasing of microorganisms that are recovered during the microbiological sample collection
12. Breeding the sample in universal microbiological culture media Ex.: casein-soy and sodium thioglycolate media, according to the United States pharmacopoeia

(The Figure 1 continue in the next page...)

* Mendonça SHF. Impacto do uso de conectores sem agulha para sistema fechado de infusão na ocorrência de infecção de corrente sanguínea, relacionada ao cateter venoso central: evidências de uma Revisão Sistemática [essay]. São Paulo: Escola de Enfermagem, Universidade de São Paulo; 2008

Evaluation criteria
13. Breeding the sample the in the shortest possible time
14. Breeding the sample in anaerobic conditions when a health care material is used in places where the presence of anaerobic microorganisms is relevant, such as oral cavity, nasopharynx, intestines, among others
15. Incubating the sample for a period which can be extended to up to fourteen days (*United States Pharmacopoeia*) For studies which aimed to evaluate alcohol function in the elimination of only mycobacteria, a 5 to 7-day period is allowed for incubation
16. Identification of species or genus of microorganisms which are detected in the sample after disinfection is not effective or efficient, in order to check whether the detected microorganism should have been eliminated through high-level disinfection
17. Inclusion of positive controls in the experiments
18. Inclusion of negative controls in the experiments
Sample size
19. Justification for the sample size, or minimum of three experiment replicates
Control of interfering external variables
20. Control of mistaken contamination (e.g., quality of the water used through processing)
Required variables which favor the reliability of studies and get tested conditions close to real practice
21. Working with comparative groups which have been either subjected or not to previous cleaning
22. In the case of experimental/laboratory studies, the contaminating agent is required to be composed of microorganisms plus organic matter

Note: all criteria must have been described in the articles. Otherwise, criteria will be deemed not met for study conduction purposes

Figure 1 - Distribution of criteria for analyzing methodological strictness of experimental/laboratory or field research, through the use of alcohol for disinfecting materials used in health care. São Paulo, SP, Brazil, 2013

Table 1 - Distribution of reasons for excluding articles and their related numbers. São Paulo, SP, Brazil, 2013

Article topic which motivated exclusion from the systematic review	Total
Related to hand sanitation	622
Antisepsis of skin	54
Disinfection of accessories for administration of medications, blood collection - such as the three way system, room for teams to administrate medications	43
Alcohol was not the main active ingredient of analyzed disinfectants	42
Repeated articles	22
Alcohol action on animal behavior	16
General characteristics of alcohol	14
General hospital-acquired infection-related issues	13
Topics regarding the food industry	13
No access to abstracts and/or to articles	13
Absence of microbiological analysis	10
Disinfectant action evaluation of alcohol on non-critical products	10
Experimental studies using pieces of metals and glass	8
Alcohol ingestion	6
Related to the disinfection of surfaces	4
Topics regarding water and air	2
Disinfectant action evaluation of alcohol on critical products	2
Systematic review which compiled data on critical and semi-critical products	1
Descriptive article, absence of microbiological association with disinfection methods	1
Total of articles which have not met the inclusion criteria	896

Results

The 14 studies that were selected for this review[6-19] were referred to as E1 to E14. Eight of them (57.2%) evaluated how effective alcohol disinfection was through field research[6-7,9-12,17,19], and eight of them (57.2%) evaluated the efficacy of alcohol disinfection through laboratory research [9,14-19].

A total 282 effectiveness tests on alcohol disinfection were conducted, out of which 104 (36.9%) microorganism growth was found. Within the 92 efficacy tests, 23 of them (25.0%) detected microorganisms after alcohol disinfection.

The number and percentage of instruments in which microorganisms were detected, and the average microbial load detected after alcohol disinfection in either previously cleaned or uncleaned products, in experimental (efficacy) or field (effectiveness) conditions, regarding the studies which were examined here may be seen in Table 2.

Table 3 shows the list of health care products which were analyzed in the studies, their total numbers and the

number of samples that were found to be contaminated after alcohol disinfection (field and experimental), as wells as the bioburden and the microorganisms detected in those samples.

According to the instrument that was created to assess methodological strictness of experimental/laboratory or field research, standardization of methods used to assess effectiveness and/or efficiency of semi-critical health care products disinfection with alcohol 70% was found to be absent, or approximate concentrations were described. The limitations of the respective studies are described in Figure 2.

Several techniques were employed to collect samples in the studies which evaluated the effectiveness and efficacy of alcohol disinfection. In the field studies, the following techniques were used: direct plating of the health care product samples in agar plates[6,10], rubbing a sterile saline solution-soaked sterile compress pad on the product[7], swab rubbing (absent description whether it was sterile or if had been soaked in a certain solution)[9], rubbing phosphate buffered saline-soaked sterile swabs on the product[12], direct inoculating the health care product in a culture broth[17], rubbing with a sterile compress pad[19]. In the experimental studies, the following collection techniques were used: soaking the health care products tubes in sterile phosphate buffered solution[8], rubbing with a Letheen broth and Tween neutralizer-soaked sterile swabbing pad[13], rubbing with a saline-solution-soaked sterile swab[14], swab rubbing (absent description regarding whether it was sterile or it had been soaked in a certain solution)[15], directly inoculating the health care product in sterile saline solution[16], direct inoculation of the health care product in a viral transportation medium[17], sterile compress pad rubbing[19]. In one of the studies that information was not described[18].

The culture media used in breeding also varied, and they were the following for the field studies: trypticase soy agar that is supplemented with defibrinated sheep blood[6], 5% blood sheep agar[8], blood agar (type not described)[9,12], 1% vitamin K and hemin-enriched blood agar[10], the kind of medium was not described in one of the studies[11], trypticase soy broth that was inoculated with trypticase soy agar, chocolate II agar, and MacConkey agar[17], sample in thioglycolate phosphate buffered solution, run through a 0.4 µm mesh sieve, and breeding the filtrate in blood agar[19]. In the experimental studies, the culture media used were the following: Middlebrook 7H11 agar (for the analysis of mycobacteria[8] agar (type not described)[13], Mitis salivarius agar, MacConkey agar, Baird Parker agar[14], brain-heart infusion agar (BHI)[15], Sabouraud dextrose agar, and BBL agar[16], Caso-Bouillon fun broth-diluted sample. After the dilution, plating with blood agar[19].

Incubation periods lasted 96 hours[6], 72 hours[7], 48 hours[10,12,19] in the field studies which intended to evaluate alcohol effectiveness. In two field studies incubation periods were not described[9,11]. In the experimental studies, incubation periods used were 24 hours[13,15], 48 hours[13,16,19]. In one field study[17] and in one experimental study[18], a 7-day incubation time was used in order to check for the elimination of a mycobacterium species.

Table 2 - Distribution of the number and percentage of health care products in which micro-organisms were detected, and average microbial load detected after alcohol disinfection in either previously cleaned products or otherwise, in experimental (efficiency) or field (effectiveness) conditions. São Paulo, SP, Brazil, 2013

Previous cleaning	Analyzed instruments (N)	No. of instruments with detected microorganisms (%)	Bioburden
Effectiveness after alcohol disinfection			
Yes	218	74 (33.9)	1 to 170 CFU/instrument and 16 to 500 CFU/mL
No	64	30 (46.9)	1 to 100 CFU/instrument*
Efficiency after alcohol disinfection			
Yes	30	11 (36.7)	8 products (<50 CFU/instrument) and 3 products (>50 CFU/instrument)
No	62†	12 (19.4)	2-54 CFU/mL‡

* Bioburden was only found in one of the four studies (E1). E1, E4, E6, and E12, which evaluated effectiveness of alcohol disinfection with no previous cleaning of products, found microorganism growth even after disinfection. One of the studies (E5) found no microorganisms after those decontamination procedures.

† The total number of analyzed instruments was not described in one of the five studies (E13). E9, E10, E12, and E13, which evaluated efficacy of alcohol disinfection with no previous cleaning of instruments, found microorganism growth even after disinfection.

‡ Bioburden was only found in one of the five studies (E8). E8, E9, E10, E12, and E13, which evaluated efficacy of alcohol disinfection with no previous cleaning of instruments, found microorganism growth even after those decontamination procedures.

Table 3 - Distribution of included studies, with their respective classifications (field or experimental) for the decontamination methods health care products (cleaning and/or disinfection) were submitted to, sample size of analyzed and contaminated materials, bioburden, and microorganisms found after disinfection with alcohol 70% (w/v). São Paulo, SP, Brazil, 2013

Study	Analyzed health care products	Previous cleaning	Type of alcohol/time for alcohol rubbing or immersion/material used for rubbing	Microorganism detection (n)/total health care products analyzed (N) (%)	Bioburden found	Microorganisms found after disinfection
E1 Field[6]	Syringes tips	No	Ethyl alcohol 70%/1 minute/does not inform material used for rubbing	10/10 (100%)	1 to 100 CFU/instrument	No identification
E2 Field[7]	Nasopharyngoscope	Yes	Ethanol 70%/rubbing time or length not informed/sterile gauze	0/100 (3 nasopharyngoscopes used in 100 patients)	N/A - no bacterial growth	N/A
E3 Experimental[8]	Gastrointestinal endoscopes (colonoscope and duodenoscope)*	Yes	Isopropyl alcohol 70%/immersed for 20 minutes in a solution at 20°C†	Duodenoscopes: 5/5 (100%) Colonoscopes: 4/5 (80,0%)	Average: 22 CFU/mL‡ Average: 16 CFU/mL‡	*Mycobacterium chelonae*
E4 Field[9]	Laryngoscope blades	No	Isopropyl alcohol 70%/rubbing/swabbing times or length not informed/swabbing on the whole surface	2/6 (33.3%)	Not informed	*Streptococcus viridans*, *Neisseria catarrahalis*, *Klebsiella*
E5 Field[10]	Periapical radiographic films	No	Alcohol 70% (type not informed)/immersion for 3 minutes	0/7	N/A - no bacterial growth	N/A - no bacterial growth
			Alcohol 70% (type not informed)/30-second rubbing/sterile gauze	0/7		
E6 Field[11]	Nasal spray (Venturi Nasal Atomizers)	No	Isopropanol 70%/rubbing time or length not informed/alcohol-soaked compress pad	1/17 (5.9%)	Not informed	*Staphylococcus epidermidis*
E7 Field[12]	Orthodontic pliers	Yes	Ethyl alcohol 70%/1-minute rubbing/sterile gauze	8/8 (100.0%)		
	Orthodontic band removing pliers	Yes	Ethyl alcohol 70%/1-minute rubbing/sterile gauze	-	After use: >500 UFC/ instrument	After use: *Streptococcus* sp., *Staphylococcus* sp. and gram-positive bacilli
					After disinfection: 400 to 500 CFU/mL	After disinfection: *Staphylococcus* sp.
	Orthodontic pliers	Yes	Ethyl alcohol 70%/1-minute rubbing/sterile gauze	8/8 (100.0%)		
	Orthodontic band removing pliers	Yes	Ethyl alcohol 70%/1-minute rubbing/sterile gauze	-	After use: >500 UFC/ instrument	After use: *Streptococcus* sp., *Staphylococcus* sp. and gram-positive bacilli
					After disinfection: 400 to 500 CFU/mL	After disinfection: *Staphylococcus* sp.
	Orthodontic Weingart pliers	Yes	Ethyl alcohol 70%/1-minute rubbing/sterile gauze	-	After use: 400 to 500 CFU/instrument After disinfection: 300 to 400 CFU/instrument	After use and disinfection: *Streptococcus* sp., *Staphylococcus* sp., and Gram-positive cocci
	Orthodontic pliers 139	Yes	Ethyl alcohol 70%/1-minute rubbing/sterile gauze	-	After use: 200 to 300 CFU/instrument; After disinfection: 100 to 200 CFU/instrument.	After use and disinfection: Micrococci
	Orthodontic distal end cutter pliers	Yes	Ethyl alcohol 70%/1-minute rubbing/sterile gauze	-	After use: 400 to 500 CFU/instrument;	After use: *Streptococcus* sp., Gram-positive bacilli and cocci negative
					After disinfection: 300 to 400 CFU/instrument	After disinfection: Gram-positive cocci and Gram negative
E8 Experimental[13]	Surgical tweezers§ with organic matter‖	No	Ethyl alcohol/30-minute immersion	1/8 (12.5%)	54 CFU/mL	*Staphylococcus aureus*
	Surgical tweezers§ without organic matter	No	Ethyl alcohol/30-minute immersion	1/8 (12.5%)	2 CFU/mL	*Salmonella cholerae suis*
E9 Experimental[14]	Orthodontic pliers¶	No	Ethyl alcohol 70%/1-minute rubbing/sterile cotton swabbing	2/10 (20%)	Authors describe significant quantities were found, but numbers are not mentioned	*Staphylococcus aureus* and *Pseudomonas aeruginosa*

(continue...)

Table 3 - (continuation)

Study	Analyzed health care products	Previous cleaning	Type of alcohol/time for alcohol rubbing or immersion/material used for rubbing	Microorganism detection (n)/total health care products analyzed (N) (%)	Bioburden found	Microorganisms found after disinfection
E10 Experimental[15]	Periapical radiographic films**	No	Alcohol 77% (type not informed)/30-second immersion	3/8 (37.5%)	Numbers not informed by authors	*Staphylococcus aureus* (1 sample) *Enterococcus faecalis* (2 samples)
			Alcohol 77% (type not informed)/60-second immersion	0/8	N/A	N/A
E11 Experimental[16]	Flexible optic fiber laryngoscopes††	Yes	Isopropyl alcohol/30-second rubbing/material for rubbing not informed	0/10	N/A - all contaminants eliminated	N/A
		No		0/10	N/A - all contaminants eliminated	N/A
E12 Field[17]	Pediatric eyelid speculum for retinopathy examination	No	Isopropyl alcohol/10-second rubbing/swabbing on the whole surface	17/24 (7.8%)	Not informed	Coagulase-negative *Staphylococcus* (16 specula), and *Bacillus cereus* (1 speculum)
E12 Experimental[17]				5/5‡‡ (100.0%) 0/5§§	Not informed	Type 5 adenovirus
E13 Experimental[18]	Goldmann tonometer||||	No	Isopropanol 70%/rubbing time or length not informed/alcohol-soaked swab	0 (total number of evaluated instruments not informed)	N/A - all contaminants eliminated	N/A - all contaminants eliminated
E14 Field[19]	Rigid endoscopes (Nasopharyngoscopes)	Yes, mechanical type, with a 5x5 sterile compress pad, soaked in 2 mL saline solution.	Isopropyl alcohol 80%/1 swipe/sterile 5x5 compress pad	57/100 (57.0%)	1-170 CFU/instrument – average of 5.5 CFU/ instrument, median of 1 UFC/instrument	*Micrococcus*, spore-forming aerobic bacteria, *Staphylococcus* spp., *Pseudomonas* spp.
E14 Experimental¶¶[19]	Rigid endoscopes (Nasopharyngoscopes)	Yes, mechanical type, with a sterile compress pad, soaked in 2 mL saline solution.	Isopropyl alcohol 80%/immersion for 15	4/10 (40.0%)	<50 CFU/instrument	*Staphylococcus aureus*
	Rigid endoscopes (Nasopharyngoscopes)		Isopropyl alcohol 80%/1 swipe/sterile 5x5 compress pad	7/10 (70.0%)	4 Instruments: <50 CFU/instrument and 3 instruments: >50 CFU/ instrument	

* Five colonoscopes and five duodenoscopes were contaminated with 1.6x106 CFU/mL Mycobacterium chelonae. The contaminating agent that was inoculated comprised no organic matter, which is found under real conditions.

† The same endoscopes were used for testing the efficacy of other disinfectants: 2% glutaraldehyde, 7.5% hydrogen peroxide, and 0.2% peracetic acid.

‡ The authors considered that the high-level disinfection was not efficient, as the initial quantity of microorganisms was reduced by 6 log10, as defined by the FDA.

§ The surgical tweezers were contaminated with a 3.0 x 108 bacteria/mL suspension with Staphylococcus aureus, Salmonella cholerae suis, and Pseudomonas aeruginosa species.

||10% fetal bovine serum was used as organic matter.

¶The orthodontic pliers were contaminated with Streptococcus salivarius, Staphylococcus aureus, and Pseudomonas aeruginosa (the authors have not described the microbial load).

** The radiographic films were contaminated with Staphylococcus aureus and Enterococcus faecalis (the authors have not described the microbial load).

†† Ten uncleaned flexible optic fiber laryngoscopes were contaminated with Staphylococcus aureus. Out of those, 5 were disinfected with isopropyl alcohol 70%and the same procedures were conducted with five flexible optic fiber laryngoscopes that were contaminated with Candida albicans.

‡‡Eyelid specula contaminated with type 5 adenovirus strains, which were bred in a minimal essential medium of 10-3 log viruses, which is considered as a clinically relevant virus titration.

‡‡ Eyelid specula contaminated with type 2 herpes simplex virus strains, which were bred in a minimal essential medium of 10-3 log viruses, which is considered as a clinically relevant virus titration;

|| ||The tonometers were contaminated with type-I HIV virus , type 1 and 2 herpes simplex virus strains.

¶¶ The nasopharyngoscopes were contaminated with Staphylococcus aureus strains.

Limitations	Studies	
	Field	Experimental
Absent description of the material used for rubbing alcohol in the health care product	E1*, E4*	E11†
Absent description regarding whether alcohol was allowed to evaporate before samples were collected	E1*, E7*	E3*, E9*, E10†*, E11†
Analysis of only part of the health care product, or missing description of analyzed parts	E1*, E4*, E7*	E9*, E11†, E14*
Absent analysis for anaerobic microorganisms, even though it applied	E1*, E2†, E4*, E5†, E7*	E9*, E10†*, E11†, E1*
Incubation period below 14 days	E1*, E2 (-)†, E4*, E5†, E6*, E7*	E8*, E9*, E10†*, E11†, E14*
Absent identification of microorganism species disinfection, even though microorganisms were detected	E1*	____
Absent identification of microorganism species that were detected in the positive control sample	E5†	____
Absent description of length of time alcohol was rubbed on the health care product	E2†, E4*, E6*	E13†
Absent description of the exact bioburden value in the positive control sample	E1*, E4*, E5†, E7*	E9*, E11†
Absent description of the exact bioburden value disinfection	E4*, E6*	E9 (+)*, E10 (+)*
Absent comparison with the previously cleaned group	E1*, E4*, E5†, E6*, E7*	E9*, E10*, E12*, E13†
Absent comparison with the uncleaned group	E2†	E3*
Absent organic load in the antigenic challenges in experimental studies	N/A	E3*, E9*, E10*, E11†, E12*, E14*
Absent validation of microorganism loading methods for sample collection	E2†, E7*	E3*, E9*, E11†, E13†, E14*
Microorganism detection in the negative control sample	E2†	------
Absent information regarding whether the alcohol solution was replaced with each procedure when disinfectant immersion methods were used	E5†	E3*, E8*, E10 30" immersion * and 60" immersion†, E14*
Absent negative control sample	E5†	E3*, E9*, E10*, E13†
Absent description of aseptic techniques used, if any	E4*, E6*	E9*, E11†, E13†
Absent description regarding the material used for sample collection	E4*	E11†
Absent validation of microorganism release methods after samples were collected, absent description regarding the use of agitation and/or sonication	E4*, E7*	E10*, E13†
Absent description of alcohol type	E5†	____
Absent description of culture medium type used	E6*	____
Absent description whether sample breeding was conducted quickly	E7*	E14*
Absent description regarding the time required to transport the sample to the laboratory, and disinfection of the health care product was only conducted in the laboratory.	E7*	____
Absent control of the confounding variable as it could possibly be contaminated (glass bottle in which a disinfected health care product was stored, covered with a kraft paper sheet during transportation)	E7*	____
Length of time during which alcohol was being rubbed on the health care product below 30" (10")	____	E12*
Absent description of number of analyzed health care products	____	E13†
Use of saline solution for previous cleaning	____	E14*

* Detection of microorganisms after alcohol disinfection

† Absent detection of microorganisms after alcohol disinfection

Figure 2 – Distribution of the methodological limitations in the studies which were included in this review. It aimed to evaluate the effectiveness and/or efficacy of disinfection semi-critical health care products with alcohol 70%, or in an approximate concentration. São Paulo, SP, Brazil, 2013

Discussion

In the health care practice, alcohol is used as a disinfectant for health care products, in order to prevent crossed transmission of microorganisms to patients in whom such products are used. This systematic review has concluded the microbiological safety of semi-critical products that are disinfected with alcohol cannot be fully ensured, as some microbial groups detected are believed to be resistant to alcohol. It's worth mentioning that, despite alcohol not being a sterilizing agent, its action promoted the full elimination of microorganisms in four studies [7,10,16,18].

Out of the fourteen[6-19] studies included in this review, thirteen[6-17,19] evaluated the efficacy and/or effectiveness of alcohol against bacteria, and two of them, against viruses[17-18]. By rubbing products with isopropyl alcohol 70%, it was not possible to eliminate type I human immunodeficiency virus, type 1 and 2 herpes simplex virus from the tips of tonometers. However, that publication failed to mention the employed rubbing time[18]. Type 1 herpes simplex virus has not been detected in pediatric eyelid specula, after isopropyl alcohol 70% was rubbed over the whole surface of that health care product for 10 seconds. However, under such conditions, type 5 adenovirus could not be eliminated from the surface of those products[17]. Adenovirus is a hydrophilic virus in which ethyl alcohol, in concentrations from 60 to 80%, should have acted

as a virucide agent[20]. An epidemic keratoconjunctivitis outbreak which is caused by type 8 adenovirus was recorded to be found in patients who got in contact with a pneumotonometer that was disinfected with isopropyl alcohol 70%[21]. Thus, studies which demonstrate the effective action of isopropyl alcohol 70% against herpes simplex virus, HIV, and adenoviruses are still considered to be scarce[20]. They also involve few samples, and were conducted in laboratory conditions[17-18,22], which demonstrates more studies are required in order to recommend isopropyl alcohol 70% in the disinfection of tonometers[20]. However, the literature does not mention the detection of type 5 adenovirus in eyelid specula, after they are disinfected with that type of alcohol, as demonstrated in this review.

In the field studies which were proposed to evaluate the effectiveness of the disinfecting action of alcohol, disinfection was not achieved for the products that had been submitted to previous cleaning (33.9%), nor was it for the ones that were not submitted to previous cleaning (46.9%). The same was verified in experimental studies in which alcohol disinfection was not achieved for 36.7% of the products that were submitted to previous cleaning, nor was it for 19.4% of the ones which were not submitted to previous cleaning. Those results do not corroborate the already consolidated recommendation that previously cleaning prior to disinfection consists of a requirement for disinfectants to have their action ensured. Nonetheless, the active ingredients of those products must directly act on dry contaminating agents in the presence of organic matter in order to be approved and registered as high-level disinfectants in the USA[5]. That represents a safety margin, due to the challenge that may be faced in the health care practice. Therefore, the effectiveness or efficacy of alcohol disinfection, even when it is conducted with no previous cleaning of instruments, is not possible to be reached, as verified in this systematic review, because organic matter is present in the health care practice, at levels which are the same or below the ones which were analyzed in laboratory tests.

Also, the reach of alcohol disinfection, in laboratory and field conditions, either with or without previous cleaning of instruments, may be related to the diversity of health care products, which are classified as semi-critical and differ both in regards to their structures and to the quantity and type of organic matter and microorganisms after such products are used. Those factors were not taken into account in 1958[1], when authors classified the articles according to their potential risk of acquiring infections, thus simplifying the potential risk levels without taking into consideration the differentiated levels that possibly existed within those categories, in particular the ones considered as semi-critical.

Scientific knowledge so far leads to a reflection on how insufficient it is to use a classification that was proposed in 1958, intended to define guidelines for the processing of articles. The type of procedures in which products have been used, and the microbial and organic load that is found in those products, after being used, are known to result in varying degrees of difficulty in regards to cleaning and disinfecting them - that fact has already been pointed out by other studies[8, 16].

In this literature review, alcohol disinfection was observed to be satisfactory for health care products such as nasopharyngoscopes (E2), laryngoscopes (E11), radiographic films (E5 and E10), and tonometer tips (E13). Those health care products do not have grooves and are not tubular; that is, they are less structurally complex and get in contact with a smaller amount of contaminants as compared to gastrointestinal endoscopes, in which alcohol disinfection was not shown to be satisfactory in this review.

Theoretically, the conduction of previous cleaning favors the action from disinfectants on microorganisms. However, the findings in this review surprisingly do not reinforce such information. In the experimental studies, the percentage detection of microorganisms in health care products, after alcohol disinfection, was higher when the instruments were submitted to previous cleaning (36,7%) as compared to situations when they were not previously cleaned (19,4%). In the field studies, the percentage detection of microorganisms in health care products was higher after alcohol disinfection when the instruments were submitted to previous cleaning (46,9%) as compared to situations when they were not previously cleaned (33,9%). However, 100 out of the 218 previously cleaned devices which were analyzed for alcohol disinfection effectiveness are nasopharyngoscopes which were used with protective covers during exams, which may optimize the cleaning and disinfection process, as the equipment does not directly get in contact with patients' mucous membranes during exams. None of those health care products was found to have microorganisms after decontamination processes. The presence of protective covers is believed to have influenced those results, and it is a characteristic which differs from the analysis of the remaining equipment. If we eliminate that variable (use of protective cover) the percentage contamination of previously cleaned, alcohol disinfected products

under field conditions would be 62.7% (74/118). Thus, in both conditions (experimental and field studies), the percentage detection of microorganisms was higher for previously-cleaned health care products. Regarding those data, it is worth highlighting that the numbers of previously-cleaned and uncleaned products tested in both groups were different - they were 218 and 64, respectively, for field studies, and 30 and 62 products, respectively, in experimental studies, which yielded higher percentage detection of microorganisms in groups with smaller quantities. Besides that, the evaluated health care products are structurally different, and so are the methodologies that were used to find and analyze microorganisms. Therefore, interpreting those data must be done with caution.

When detected bioburden in the products which are either submitted or not to previous cleaning prior to disinfection in experimental and field conditions are evaluated, nothing can be said with certainty, as different units of measurement were used (CFU/mL and CFU/instrument) and the bioburden that were detected in products for which disinfection was not effective or efficacy are not informed.

In this review, the methods used for alcohol application were rubbing and immersion, as shown in Table 3. The method regarding immersion in alcohol is not often used in the health care practice, and one of the reasons for that is the volatility of that disinfectant, which leads to the need of replacing solutions with each use. However, that procedure was not described in two studies using the immersion method.

Strictly observing the time period through which health care products were exposed to alcohol is one of the basic requirements for this disinfectant to perform accordingly. The studies analyzed in this review used rubbing times which ranged from 10 seconds to 1 minute. In the ones using immersion methods, immersion times ranged from 20 seconds to 20 minutes. Among the five studies in which alcohol action resulted in the full elimination of microorganisms (E2, E5, E10, E11, E13), one of them (E5) used a 3-minute immersion time and a 30-second rubbing time. Another one (E11) also used rubbing, for 30 seconds. In study E10, the immersion time was 60 seconds, and in other two studies (E2, E13), time of alcohol exposure was not described. Variations in rubbing and immersion times that were found in the studies made it difficult comparing or defining optimal exposure times for products to alcohol. In one study**, application of alcohol 70% (m/v) in high-rotation dental drills (HRDD) for 90" after HRDDs had been intentionally contaminated with 10^6 CFU/mL *S. marcescens* resulted in the best contact time for a germicide to reduce the initial bioburden, through the use of a validated methodology with a single gauze pad for dragging microbes out of the external HRDD surface.

Several health care products with different risk levels within the semi-critical category were analyzed in this review, from tubular devices such as endoscopes, and ones with flat surfaces and without grooves, such as periapical radiographic films, which made comparing results difficult. Besides that variable which made it difficult comparing obtained results, others may be mentioned, such as different techniques for microbiological sampling, different materials used for rubbing the alcohol, distinct methods for breeding and identifying microorganisms, and sample size variations.

Conclusion

The results from this systematic review demonstrate that disinfection of semi-critical health care products with alcohol 70%, or in an approximate concentration, is not generally safe, with regards to the possibility of exposing patients to microorganisms (bacteria and viruses) which remain in those instruments even after they are disinfected. However, disinfection of semi-critical products with alcohol 70%, or in an approximate concentration, may be reached for both products that are previously cleaned and for the ones which are not.

The diversity of products and results found in this review leads one to believe that disinfection procedures may be different according to the structural complexities of semi-critical materials, as well as according to the microorganism load, organic, and inorganic residue those products may carry after being used. Absent complexity in semi-critical health care product structures (no grooves, no tubular shapes) may be a factor that contributes for satisfactory disinfection with alcohol 70%, or in an approximate concentration - regardless if products are previously cleaned or otherwise.

Standard protocols are observed to be required to be created and published, in order that tests for

** Pinto FMG. Desinfecção das canetas de alta rotação com álcool 70% p/v [thesis]. São Paulo: Escola de Enfermagem, Universidade de São Paulo; 2013.

evaluating the effectiveness and efficacy of disinfectants be conducted. Those protocols are suggested to include the items used in the studies, so the methodological strictness of studies can be evaluated.

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