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Evaluation of Two Different Methods of Hand Disinfection, Sterillium® Compared with Hibiscrub®: The Experience from Sweden

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ABSTRACT

Introduction: Post-operative infections are a major issue in healthcare. Not only do these infections strain the budget, but they also cause thousands of patients a great deal of suffering. Research showed that postoperative infections can be prevented. Preoperative hand disinfection is one of these preventative measures.
Aim: The aim was to compile scientific studies in which the difference in effectiveness between two hand disinfectants is evaluated; the alcohol-based hand disinfection method and the antiseptic method.
Method: The method used was based on seven scientific articles. These articles were selected through a systematic search of the following databases: CINAHL, PubMed and Scopus. All comparisons between the two hand disinfection methods, and any discussion thereof, were approached with surgical site infection (SSI), the number of bacterial colonies (CFU/ml) and skin reaction in mind.
Result: The result in the study shows that the alcohol-based hand disinfection method (SHR), in combination with (Sterillium®), is significantly more effective than preoperative antiseptic hand disinfection method (SHS) using (Hibiscrub®). The systematic literature review shows that the credibility of the included articles is rather high; they are within the low, the middle high and high evidence range.
Conclusions: The alcohol-based disinfection method with Sterillium® was more effective than the preoperative antiseptic hand disinfection method with Hibiscrub®. Development and research in the field are constantly evolving and thereby subject to change. It is therefore important to research the various interventions that produce better results, and that can be tested and compared in as many surgical departments as possible worldwide.

Keywords: Handwashing, hand scrubbing, surgical scrubbing, surgical infection, infection control

INTRODUCTION

Well-executed hand hygiene among healthcare professionals in patient-related work is the most important measure to prevent the spread of infection. Hands that are unclean can transmit bacteria and viruses to patients, which can cause infections, which in turn can lead to the patient suffering and a prolonged hospital stay for the patient. [1] According to WHO, [2] millions of people worldwide are infected every year by infections that arise in connection with care and treatment. In Sweden, according to the Public Health Authority (2018), every tenth patient in Swedish hospitals has been affected by a healthcare-acquired infection or a healthcare-associated infection (HAI or HCAI), [3] which is usually caused by the spread of infection. [4-6] According to WHO, hundreds of millions of people worldwide are affected by HAI every year. [7,8] HAIs

affect between 3.5% and 12% of the population in high-income countries compared to low-income countries, where between 5.7% and 19.1% of the population suffer. [2,9] HAI causes about 750,000 extra care days per year, at a cost of approximately SEK 6.5 billion. [10] A study by Aldeyab et al. (2014) [11] shows how the proportion of multi-resistant bacteria increases in HAI, where multi-disease patients, due to their impaired immune systems are more vulnerable to this type of infection in intensive care. When it comes to spreading bacteria to patients, a another study by Megeus et al. (2015) [12] shows that pathological endogenous and exogenous microorganisms can be spread to the patient from people in different occupational categories in the operating room due to incorrect hand hygiene. WHO has issued guidelines for aseptic technology and how various products can be used in perioperative hand disinfection. [2] These guidelines also discuss early perioperative hand disinfection methods to compare them with today's aseptic techniques and hand disinfectants, both alcohol-based and antiseptic agents. [13] A study by Jayaraman et al. (2014) [14] has shown that hand hygiene is the most important factor in reducing the risk of infections during surgical procedures, and that businesses should work to ensure that all healthcare professionals follow the established guidelines for good hand hygiene. With a good hand disinfection method and thereby the reduction of HAI, the use of antibiotics can be minimized. [11] Different types of hand disinfectants are used in health care. Some agents are based on 70% alcohol and others on soap and water only. Alcohol-based products have shown better efficacy in studies than, for example, only soap and water. [15,16] In surgical and intensive care, it is important that the most effective products are used to achieve the best aseptic hand hygiene possible. [11,14] A study by Deshpande et. al (2018) [15] compared two different hand disinfectants, ethanol mixed with chlorhexidine gluconate, and ethanol alone, used in intensive care. The purpose of this study was to compare the immediate but also the lasting effect of these agents. The results showed that hand disinfectants containing only ethanol had better efficacy. By and large, it was found that there are two methods of cleaning hands before an operation. One method consists of an alcohol-based hand disinfectant (Sterillium®), and the other is an antiseptic hand disinfectant (Hibiscrub®). [17-19] A previous study done in Sweden shows that the operating nurse, as a member of the surgery team, should have good knowledge about patient safety and infection control, and preventive measures of post-operative wound infections(SSIs). [12] HAIs are a major problem in healthcare worldwide and also in Sweden. It is not just about the huge costs, but above all, the great suffering, both physical and mental, for the patients affected. Both the material consequences and the human suffering that follow from health-related infections are a strong reason to expand the research on the subject. There are various methods of preoperative hand disinfection to prevent infections. The problem now is which method is the most effective for reducing hand contamination. Therefore, the aim of the present study was to compile, through a structured literature study, scientific studies in which the difference in effectiveness of two hand disinfectants is evaluated: the alcohol-based hand disinfection method (SHR) with Sterillium® and the antiseptic method (SHS) with Hibiscrub®.

MATERIAL AND METHOD

The present study was based on a literature review. The criteria for inclusion of the articles consisted of the following inclusion criteria: that they were in English, published after 2000, and fulfilled the requirements of science. By the latter we mean that the results must be both controllable and reproducible. The inclusion criteria also included that the articles had compared the two hand disinfectants / methods that underlie this study. The first

exclusion was made after reviewing the titles of the articles. The articles that did not meet the PICO and other eligibility criteria were removed as shown in (**Figure 1)**.

P	Surgery personal and patient to underwent procedures.
I	Alcohol-based hand disinfection method (Sterillium®)(SHR)
C	Antiseptichand disinfection method (Hibiscrub®)(SHS)
O	Surgical site infection (SSI) Bacterial colonies (Colony- Forming Unit =CFU) Skin reactions Sepsis Mortality

Figure 1. P = Patient/population/ problem, I = Intervention, C= Comparison/ control and O = Outcome

The next exclusion occurred in the abstract reading and the articles that were not considered relevant were excluded. The latter were related to veterinarian, were reviews, letters and reports, or were subject to fees. The search led to further exclusions. Different combinations were made with the following keywords: Cinhal, Cinahl headings (hand washing, hand scrubbing and surgical scrubbing), PubMed, MeSH terms (hand sanitizers, surgical handwashing, infection and infection control) as well as (Hibiscrub® and Sterillium®), Scopus, all terms (hand, handwashing, sanitizer, surgical, scrub and disinfection). All literature searches in the databases are reported in Appendix 1. The articles were reviewed by a person (FK) at the title and abstract level, then the full text of the articles was read by the same person. The articles were reviewed and compared with each other for similarities and differences. For the scientific and quality review of the articles, the State's preparation for medical and social evaluation (SBU's) [20] method of review was used.

RESULTS

The literature search in the present study was conducted in three databases with specific keywords that were adapted to the purpose of the current study. The literature search led to the identification of four RCTs (Randomized controlled study), one RCO (randomized crossover study) and two comparative studies. The flowchart (**Figure 2**) shows the result process.

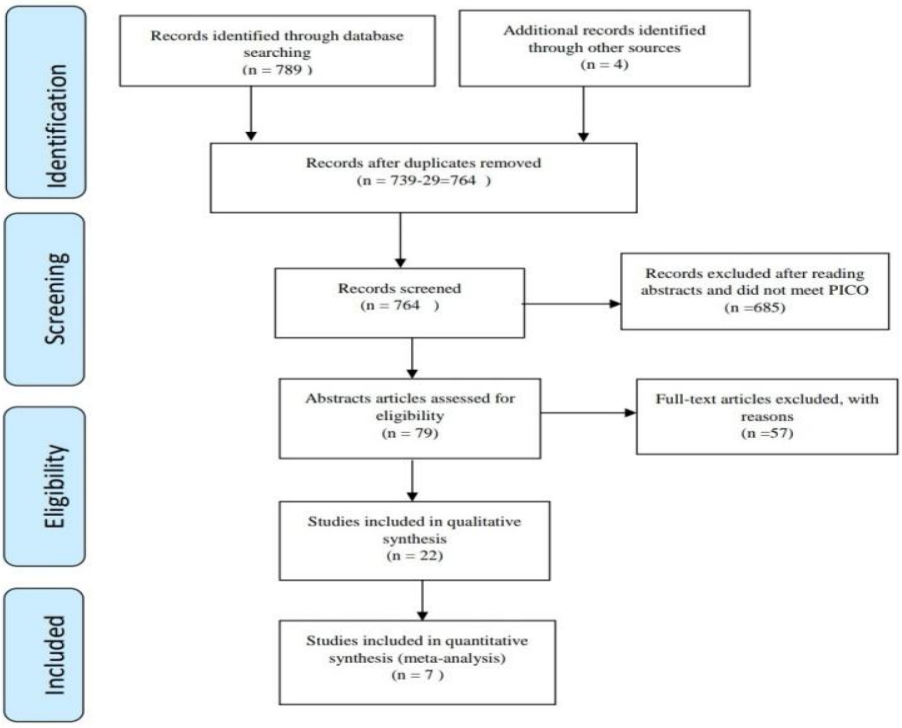

Figure2. PRISMA flow diagram.

All searches, including secondary literature (articles that have been selected indirectly, for example through reading another study's source material) yielded 793 hits, of which 29 were common and 685 were not relevant to the title (did not meet PICO and other eligibility criteria, according to Appendix 1). Of the 79 hits, 57 were excluded because they were either not relevant to the purpose of the study, they were related to veterinary medicine, were reviews / letters / reports or required a fee. After full-text analysis of the last 22 articles, 7 articles were included, the articles which were considered to be most relevant for the present study. Four RCT studies investigated the effects of alcohol based (SHR) and antiseptic hand infection methods (SHS), the RCO study compared Sterillium® and Hibiscrub®, the two comparative studies also investigated SHR and SHS. The participants in all seven articles belonged to the surgery team or were patients. The target population was treated with two different hand disinfection methods. Three of the selected studies were judged to contain high evidence; three studies had moderate evidence, while one of the articles was judged to have low evidence, (Table 4 or SoF- Table). In the in-depth studies there were no evaluations of mortality and sepsis.

Postoperative wound infection (SSI)

Table1: Result variable: SSI

Study, Year and Country	Study Design and Type of surgery	Number of op. Staff n=	Missing data	Results			Risk for selections bias	Ethical approval
				I= Sterillium®	C=Hibiscrub®	P - value		
Al - Naami et al. 2009 Saudi Arabia	RCTGeneral and robot	I = 228 C = 272	0	2.94 %	5.3 %	0.28 P> 0.05	Ⅰ	Included
Jean Jacques Parienti et al. 2002, France	RCT General, Urology, Gynaecology and Orthopaedic	I = 313 C = 287	155	2.44 %	2.48 %	19.5 P< 0.001	Ⅱ	Not clarified

Ⅰ = High level of evidence, fills the SBU criteria low risk of bias

Ⅱ = Medium high degree of evidence, Does not meet all SBU criteria and thus there is a risk of bias.

Ⅲ = Low level of evidence, major shortcomings in fulfilling the SBU criteria.

Regarding SSI, two RCT studies, Al-Naami et al. (2009) [21] and Parienti et al. (2002) [22] showed SSI results (See Table 1). In the studies by Al-Naami et al. (2009)(21) and Parienti et al. (2002), [22] the number of SSIs was extensively described and listed in a table. The results of the study by Al-Naami et al. (2009) [21] showed that 12 (5.3%) of patients in SHS (Hibiscrub®) were affected by SSI, while in the other group SHR (Sterillium®), the figure was 8 (2.94%). The results showed that the alcohol-based hand disinfection method was better than the other. Most surgeons (64%) preferred SHR to SHS. However, the results in Parienti et al. (2002) [22] did not show a significant difference between the methods. The number of patients affected by SSI in the alcohol-based hand disinfection group was 55 out of 2252 (2.44%) and in the other group it was 53 out of 2135 (2.48%). The study was conducted in six hospitals and 77 departments. The study by Al-Naami(2009) [21] was judged to have a high degree of evidence, according to SBU (see Table 4 / SoF-table). The second study, Parienti et al.(2002) [22] had a risk of bias in the study (Table 4).

Number of bacterial colonies (CFU)

Studies whose results indicate the number of CFUs or the effectiveness of hand disinfection methods are presented in Table 2. The study byHoward J et al.(2014) [23] shows no significant difference between the amounts of bacterial colonies (CFU) on the hands of each group. The same results are shown in the second RCT study, by Tsai et al. (2017). [24] Forer, Block and Frenkel (2017) [25] reported colony forming units (CFU / ml) and differences between hand disinfection

methods. No significant difference was found between the bacterial colonies in the two groups. The study showed that there is a certain difference between routine use of SHS and SHR in terms of the distribution of bacterial colonies. The conclusion was that alcohol-based hand disinfection is significantly more effective than SHS. The comparative study, by Lopez-Gigosos et al. (2017), [26] showed that SHR (Sterillium®) has better efficacy compared to SHS (Hibiscrub®). This study contains four sub-studies. No products showed long-lasting effects. It should be added that the study only reports laboratory results. Pietsch (2001) [27] states measurementsof CFUsbut lacks a connection to SSIs. The study shows some significant differences between the two groups regarding SHS and SHR. The study by Howard j et al. (2014) [23] had high evidence value, according to SBU criteria. Tsai et al. (2017) [24] and Lopez-Gigoses et al. (2017) [26] were judged to be of moderate evidence value because, according to SBU criteria, there was a risk of bias. The Forer, Block and Frenkel (2017) [25] study had a low risk of bias; therefore it received a high degree of evidence. In the study by Pietsch (2001) [26] with low evidence value, a clear explanation of the method was missing, the research result was also not blinded, and no ethical position was considered.

Table 2: Result variable: CFU

Study, Year and Country	Study Design and Surgery Type	Number of op. Staff n=	Missing data	Results			Risk for selections bias	Ethical approval
				I= Sterillium®	C=Hibiscrub®	P - Value		
Howard j. Jowett C. Faoagali J. Mckenzie B. 2014 Australian	RCT Not given	I = 20 C = 20	0	2.01 ± 0.98	1.45±0.50	P>0.05	I	Included
Jui-Chen Tsai 2015 Taiwan	RCT General, Cardiac and vascular, plastic, Urology, Gynaecology, Orthopaedic Neurology, Eye and Otorhinolaryngology	I = 80 C = 80	4	1.4 ± 0.8	0.8 ± 0.8	0.0036 P<0.01	II	Prerequisitesfor ethical approach have carried out.
López Gigosos 2017, Malaga Spain	Comparative study Not given	I = 20 C = 20	0	1 min 2.3 ± 0.6 30 min 1.8 ± 0.7 60 min 1.2 ± 0.6 90 min 0.9 ± 0.6	1 min 3.5 ± 0.9 30 min 3.1 ± 0.4 60min 3.2 ± 0.8 90min 2.8 ± 0.5	P< 0.05	II	Included
Pietsch, 2001 Germany	RCO General, Neurology and Kidney transplant	I = 75 C = 75	0	2.4 ± 0.13	1.3 ± 0.12	P<0.0001	III	Not clarified
Yarra Forer, 2017, Jerusalem, Israel	Comparative Eye	I = 20 C = 20	0	1.59 ± 1.12	3.08 ± 0.65	0.97 P<0.0001	I	Included

Skin reactions

In the study by Al-Naami et al. (2009), [21] the number of skin reactions is stated in tabular form, but without reporting which scale / tool was used in the study. A total of 40 (17.5%) skin reactions occurred in the surgical SHS group and 31 (11.4%) reactions in the SHR group. Most surgeons (64%) preferred SHR over SHS. Parienti et al. (2002) [22] describe how skin tolerance is affected by the different hand disinfection methods. The result showed

a decrease in skin dryness of 0.9 cm (95% CI, 0.5-1.2) after SHR. In the study, skin dryness and irritation were measured using a tool -a visual analogue scale (VAS from 0 cm to 10 cm (0 on this scale indicates no skin tolerance while 10 stands for maximum skin tolerance of skin dryness)) and 95% CI (confidence interval between SHR and SHS group). Skin dryness then increased by 0.4 cm (95% CI, -0.1 to 1.2) after SHS, (P = 0.046). Skin irritation value decreased by 1.5 cm (95% CI, 1.1-1.9) after SHR, but increased by 0.4 cm (95% CI, 0.2-0.6) after SHR, (P = 0 .03). A surgical operations nurse was reported to have had both hand and eye irritation with SHR. Pietsch (2001) [27] reports the amount of skin damage caused by hand disinfectants / methods. All lapses occurred because of skin damage.

Table 3: Skin reactions

Study, Year and Country	Study design and type Surgery	Number of op. Staff n=	Missing data	Results			Risk for selections bias	Ethical approval
				I= Sterillium®	C=Hibiscrub®	P – Value		
Al - Naami et al. 2009 Saudi Arabia	RCT	I = 228 C =272	0	31 (11.4%)	40 (17.5%)	0.067	Ⅰ	Include
Jean Jacques Parienti et al. 2002, France	RCT	I = 313 C = 287	155	Decrease skin dryness 0,9 cm (95 % CI, 0.5-1.2) Decreaseskin irritation 1,5 cm (95 % CI, 1.1–1.9)	Increase skin dryness0,4 cm (95 % CI, 0.1 to 1.2) Increase skin irritation 0,4 cm (95 % CI, 0,2-0,6)	0.008	Ⅱ	Not clearly stated
Pietsch, 2001 Germany	RCO	I = 30 C= 30	16	Ca 1.4 %	20 %	Not given	Ⅲ	Not clarified

Table 4. Summary of results (SoF-Table)

Results	Study design and number	Results	Quality of evidence according to SBU – malls
Mortality	0	0	0
Sepsis	0	0	0
SHR against SHS			
SSI	RCT	SHR = 2.94 % vs	Evidence Grade= Ⅰ
	(21)	SHS= 5.3 %	
	RCT	SHR = 2.44 % vs	Evidence Grade= Ⅱ
	(22)	SHS= 2.48	
SHR against SHS			
Number of CFU	RCT	SHR = 2.01 ± 0.98	Evidence Grade= Ⅰ
	(23)	SHS = 1.45±0.50	
	RCT	SHR = 1.4 ± 0.8	Evidence Grade= Ⅱ
	(24)	SHS = 0.8 ± 0.8	
	RCO	SHR = 2.4 ± 0.13	Evidence Grade= Ⅲ
	(27)	SHS = 1.3 ± 0.12	
	Comparative	SHR = 1.59 ± 1.12	Evidence Grade= Ⅰ
	(25)	SHS = 3.08 ± 0.65	
	Comparative	SHR = 2.3 ± 0.6	Evidence Grade= Ⅱ
	(26)	SHS = 3.5 ± 0.9	
SHR against SHS			
Skin reactions	RCT	SHR = 31 (11.4%)	Evidence Grade= Ⅰ
	(21)	SHS = 40 (17.5%)	
	RCO	SHR = Ca 1.4 %	Evidence Grade= Ⅲ
	(27)	SHS = 20 %	
SHR against SHS			
Skin reactions	RCT	SHR dryness 0.9 cm (95 % CI. 0.5-1.2)	Evidence Grade= Ⅱ
	(22)	SHR irritation 1.5 cm (95 % CI. 1.1–1.9)	
		SHS dryness0.4 cm (95 % CI. 0.1till 1.2)	
		SHS irritation 0.4cm (95 % CI. 0.2-0.6)	

Ⅰ = high, Ⅱ = medium and Ⅲ= low

DISCUSSION

Methodological discussion

The method used in this study was a structured literature study, based on a systematic analysis of seven scientific articles. The actual process of selecting these articles is based on the inclusion and exclusion criteria chosen. In the present study, we followed the book "Nursing Research" by Timmins (2013), [28] who recommends a number of factors that must be considered if you want to perform a systematic literature study. In such studies, the degree of evidence of the included articles should be carefully evaluated to arrive at a credible result. Furthermore, the study will investigate whether there is a risk of bias. It is, among other things, by considering these factors that the selected articles may be evaluated. The studies that are judged to be of a high degree of evidence provide more strength to the results than those that have low levels of evidence. [29] With regard to the selection method and the quality assessment, SBU's review method [20] was used. The studies that received SBU points for a high degree of evidence had high credibility in their conclusions. These studies also had less risk of different types of bias than those studies that received average and low evidence assessments. Thus, a study with a low level of evidence was of low value in terms of credibility or science. However, it should be added that the grades awarded (I, II and III) were set by the authors of this study. It is thus possible that another study, with another author, and another assessment model could come to a different result. However, well-tested assessment models, such as SBU's model, prevent an overly arbitrary evaluation. All the articles selected were written in English and published after 2001. The purpose was to provide the very latest and most up-to-date discussion of the hand disinfection problem. The fact that all articles were written in English means that the author himself translated their contents into Swedish. This means that a subjective position was taken when it comes to interpreting the content of the selected articles. The purpose of this study was to compare and discuss two different methods / means to reduce hand contamination. Here, too, it became necessary to delineate the areas that were felt to be relevant for such a comparison. The following factors were then taken into account: postoperative wound infection (SSI), number of bacterial colonies (CFU / ml) and skin reaction. This means that other factors may have been overlooked or discussed on the basis of other aspects. The question was simply which questions were asked about the material and what answers were expected.

Discussion about the results

The purpose of the thesis was to compile current studies comparing the disinfectants Sterillium® and Hibiscrub®. The main results indicate that the alcohol-based hand disinfection method is more effective than the antiseptic method. However, it is not possible to state that this is an undeniable conclusion. In the future, new studies may very well change the "truth" that applies today. In some of the studies, other disinfectants were also used than the two here. They showed that SHS was more effective than SSI, CFU / ml and skin reactions achieved on average showed good results in the SHR group, which are reported in the respective table. On the basis of this study's review, the articles by Al-Naami et al. (2009), [21] Forer, Block, & Frenkel (2017) [25] and Howard et sl. (2014) [23] received a high degree of evidence which means high credibility, and low risk of bias. The studies by Lopez-Gigosos et al. (2017), [26] Parienti et al. (2002) [22] and Tsai et al. (2017) [24] received a medium degree of evidence, which means a slightly higher risk of bias. The study by Pietsch (2001) [27] that was judged to be of low evidence, had the greatest risk of bias. Some of the studies showed that the SHS group was better at reducing contamination, [22,23,27] while other studies found that no difference could be detected between SHS and SHR. [25,26] In those studies that only used laboratory tests, one or the other method was recommended,

but it should be noted at the same time that these studies had no link to clinical implications, e.g. connection to the number of SSIs. In the results of these studies, the antiseptic method was considered to produce fewer SSIs. In some of the studies, it was established that alcohol-based hand disinfection methods led to fewer SSIs. [21,30,31] However, the results of other studies showed that there is no significant difference between the methods [22,25-27] With regard to skin reactions, some of the studies showed that there are some differences between the methods, where alcohol-based hand disinfectants had the least impact on the skin. [21,22,27] On the other hand, the studies by Asensio & De Gregorio (2013)and Parienti et al. (2002), [22,30] showed that there is no significant difference in skin reactions between SHR and SHS. Taken together, it can be said that the results from a predominant number of studies indicated that alcohol-based hand disinfection with Sterillium® was better and more effective than antiseptic hand disinfection with Hibiscrub®. According to the recommendations of today's healthcare system, surgical personnel use two disinfectants (Sterillium® and Hibiscrub®). The hand hygiene routine of surgical personnel is very important in surgical operations to prevent postoperative SSIs. [30-32] Asensio & De Gregorio (2013) [30] point out in their study results that show that most surgical staff believe that SHR is more effective in reducing hand contamination, and the main reason for not using AHR is that it leads to skin reactions.

CONCLUSION

On the basis of the articles that formed the basis for this systematic literature study, it was found that the alcohol-based disinfection method with Sterillium® was more effective than the preoperative antiseptic hand disinfection method with Hibiscrub®. The quality of the included articles was judged by their credibility regarding low / medium / high evidence. However, on the basis of this study result, it is not possible to establish that the alcohol-based hand disinfection method would be the absolutely best method. Other studies in the future may show different / revised results. In other words, the present result must be viewed in the light of the current state of knowledge. Development and research in the field are constantly evolving and thereby subject to change. The study limitations, for example that a literature review was conducted by one person, must also be taken into consideration. In the present study, two different methods / means were used to evaluate preoperative hand disinfection among surgical staff. However, there may be many other interventions that would produce even better results. It is therefore important to research the various interventions that produce better results and that may be tested and compared in as many surgical departments as possible worldwide. The author of this study therefore considers that a compilation of all the research results both nationally and internationally is needed.

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