AN INVESTIGATION INTO

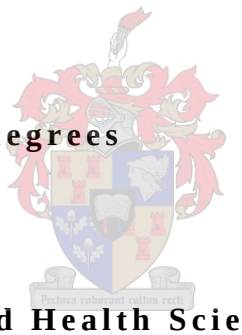
THE USE OF CONDOMS

AS ULTRASOUND PROBE COVERS DURING STERILE PROCEDURES

Thesis presented by

Nayandra Runveer Sooraj

MBChB (Stell) DA (SA)



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Promoter: Dr. F. W. Retief

MBChB (Stell), DA (SA), PPD (UWC), FCA (SA), MMed (Anaes)

Department of Anaesthesiology and Critical Care

Faculty of Medicine and Health Sciences

Stellenbosch University

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1. **DECLARATION**

I declare that I was involved in all phases of this study from conception to execution, that the work is my own with the declared acknowledgement to the above study leaders and technical support.

To the best of my knowledge the dissertation complies with the University of Stellenbosch regulations on Plagiarism.

Signed:

Nayandra R Sooraj

2. ACKNOWLEDGEMENTS

I wish to thank Professor Andrew Whitelaw, Mrs Joan Basson and Miss Justine Masamba from the Tygerberg NHLS Microbiology Department for the guidance and support during the project.

I sincerely appreciate the helpful comments and contribution of Dr Francois Retief and Prof Andrew Levin.

I would also like to thank Mr Justin Harvey for assisting with the statistical analysis.

3. ABSTRACT

Purpose

The purpose of this study was to investigate the use of condoms as an alternative to commercially available ultrasound probe covers for the maintenance of sterility during ultrasound-guided medical procedures. We hypothesised that condoms are sterile in their packaging and are effective barriers to bacterial translocation during sterile procedures.

Methods

Phase 1 examined whether condoms are sterile in their packaging. Ten condoms were removed from their packaging under sterile conditions and placed into nutrient broth. After 24 hours of incubation, they were checked for turbidity as a measure of contamination.

The second phase of the study examined the ability of condoms to prevent translocation of bacteria from heavily contaminated probe head models to growth media. The experimental model was designed to simulate clinical conditions. Rectangular glass coplin jars were dipped into KY jelly inoculated with *Klebsiella* and *Staphylococcus*. Condoms were subsequently placed over the ends of the jars. After a brief exposure period, the condoms were removed carefully and the uncontaminated tips dipped individually into different 20ml containers of nutrient broth. The containers were then incubated for 24 hours, after which they were examined for turbidity as an

indicator of bacterial translocation. The experiment was conducted using sterile precautions akin to procedures performed in operating theatres.

Results

In the first phase, one of the ten condoms (10%; 95% confidence intervals 0.3% - 45%) showed bacterial growth.

In the second phase, 18 of the 30 samples (60%; 95% confidence intervals 41% - 77%) showed bacterial growth.

Conclusion

The results of the study suggest that the use of condoms, as sterile ultrasound barriers, may not prevent translocation of bacteria in clinical practice. A number of factors may influence the effectiveness of condoms, such as the probe head size, bacterial load and manufacturing quality of the condom. Further studies are needed to compare condoms to commercially available probe covers.

4. OPSOMMING

Doel

Die doel van hierdie studie was om die gebruik van kondome as 'n alternatief vir kommersieel beskikbare ultraklank-sonde bedekkings vir die instandhouding van steriliteit tydens ultraklank-begeleide mediese prosedures te ondersoek. Ons hipotese is dat kondome steriel is in hul verpakking en dat kondome doeltreffende hindernisse is tot bakteriële translokasie tydens steriele prosedures.

Metodes

Fase een ondersoek of kondome steriel is in hul verpakking. Tien kondome is uit hul verpakking onder steriele omstandighede verwyder en in voedingskultuur geplaas. Na 24 uur van inkubasie, is hulle nagegaan vir troebelheid as 'n maatstaf van kontaminasie.

Die tweede fase van die studie ondersoek die vermoë van kondome om translokasie van bakterieë te verhoed vanaf swaar besmette ulraklank-sonde modelle. Die eksperimentele model is ontwerp om kliniese toestande na te boots. Vierkantige glas coplin flesse is gedoop in KY jellie ingeënt met Klebsiella en Staphylococcus. Kondome is daarna oor die punte van die flesse geplaas. Na 'n kort blootstelling tydperk is die kondome versigtig verwyder en die onbesoedelde punte individueel gedoop in afsonderlike 20ml houers met voedingskultuur. Die houers is daarna geïnkubeer vir 24 uur, waarna hulle vir troebelheid ondersoek is, as aanduiding van bakteriële

translokasie. Die eksperiment is uitgevoer met steriele voorsorgmaatreëls, soortgelyk aan prosedures in operasiesale.

Resultate

In die eerste fase het een van die tien kondome (10%, 95% vertrouensintervalle 0,3% - 45%) bakteriële groei getoon.

In die tweede fase het 18 van die 30 monsters (60%, 95% vertrouensintervalle 41% - 77%) bakteriële groei getoon.

Gevolgtrekking

Die resultate van die studie dui daarop dat die gebruik van kondome as ultraklank-sonde bedekkings, moontlik nie translokasie van bakterieë voorkom in die kliniese praktyk nie. 'n Aantal faktore kan die doeltreffendheid van kondome beïnvloed, byvoorbeeld die grootte van die sonde, die bakteriële lading en vervaardigingskwaliteit van die kondome. Verdere studies is nodig om kondome met kommersieel beskikbare bedekkings te vergelyk.

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5. INTRODUCTION

The fields of anaesthesia and critical care are fast growing new-users of ultrasound technology. Anaesthesiologists often use ultrasound to guide procedures and some of these require strict sterile technique. Examples include placement of central venous (2,7,21) and perineural catheters.(20)

Sterile protocols are used to ensure aseptic conditions. These protocols include appropriate cleaning agents, barrier protection for the procedurist (sterile gloves, mask, and sterile gown) and sterile draping over the area of interest.(7,21)

The addition of the ultrasound probe complicates matters. At best, probes can be cleaned with sterile saline, as any other material such as alcohol can affect the functional integrity of the probe. There is evidence that the acoustic gel (used to improve image quality) may also act as a culture medium for bacterial growth and lead to nosocomial infection.(8,11,19) Therefore one would need a sterile cover that allows ample manipulation of the probe without sacrificing sterility or image quality. Probe covers that meet the above requirements are commercially available, such as Parker probe covers. They are, however, expensive and not freely available in the South African public healthcare sector.

Alternative probe covers used in our institution include sterile gloves and transparent film dressings, such as Tegaderm™ (3M Healthcare Minnesota, USA). Other centres have even reported using sterile Clingwrap plastic film.(15) One intuitive option that has not yet been explored is the use of condoms to cover ultrasound probes. (18)

Our knowledge of the effectiveness of condoms is founded on studies related to the prevention of pregnancy and sexually transmitted diseases, and in particular, HIV transmission. The effectiveness of condoms in preventing pregnancy is estimated between 90.7% and 98.6%, the breakage rate during vaginal or anal coitus is 2%.(26) The overall effectiveness of condoms in reducing the seroconversion rates of HIV is reported to be 80%.(27) Condoms have also been used as a barrier in other medical procedures, having a 9% perforation rate when used in trans-rectal ultrasonography.(18)

South Africa has one of the highest rates of HIV infection in the world. One of the strategies of the government is to provide free condoms to the public. These are freely available in restrooms in public areas, including hospitals. The purpose of this study was to explore the option of using this government issued Choice™ condoms (SFH, Johannesburg, South Africa) as a sterile barrier during ultrasound-assisted procedures. It would appear logical that if these devices can prevent HIV transmission (0.12 micron) they would also prevent transmission of larger bacteria (0.5-5 micron).

While South African Bureau of Standards (SABS) approved, the product's sterility has not been documented. Therefore the first aim of this study was an investigation into the sterility of government issued condoms.

The second aim of the study was to investigate the condom's barrier properties in terms of its ability to prevent bacterial translocation under laboratory conditions.

6. HYPOTHESES

The first hypothesis states that condoms are sterile in their packaging.

The second hypothesis states that condoms are effective bacterial translocation barriers.

7. MATERIALS AND METHODS

7.1.1 Ethical approval for the study

Approval for the study was granted by the Health Research Ethics Committee of Stellenbosch University (S14/01/015).

7.1.2 Facilities

This study was conducted with the assistance of the Department of Microbiology at Tygerberg Academic Hospital in the Western Cape province of South Africa.

7.1.3 Condoms

Government issued Choice™ condoms were investigated in this study. These were sourced from condom dispensers from Tygerberg Academic Hospital during October 2014 and expiry dates checked. The packaging of each condom was checked and found to be intact prior to usage.

7.2 Examining condom sterility

Using a sterile technique, ten condoms were removed from its packaging and placed in separate 20ml containers filled with nutrient broth and incubated for a period of twenty four hours. The sterile technique for removing the condom from its packaging was as follows: Using a non-touch technique, an assistant opened the condom wrapper. The condom was removed from its packaging and placed into the nutrient broth, using sterile gloves and an autoclaved forceps. After 24 hours of incubation, the samples were examined for turbidity, as an indication of bacterial growth. It was accepted that the condom was sterile when no turbidity in the nutrient broth was observed. Any turbidity was interpreted as indicating that the condom was not sterile.

7.3. Examining the effectiveness of condoms as a sterile barrier

The ability of condoms to provide protection against bacterial translocation was tested in a laboratory setting.

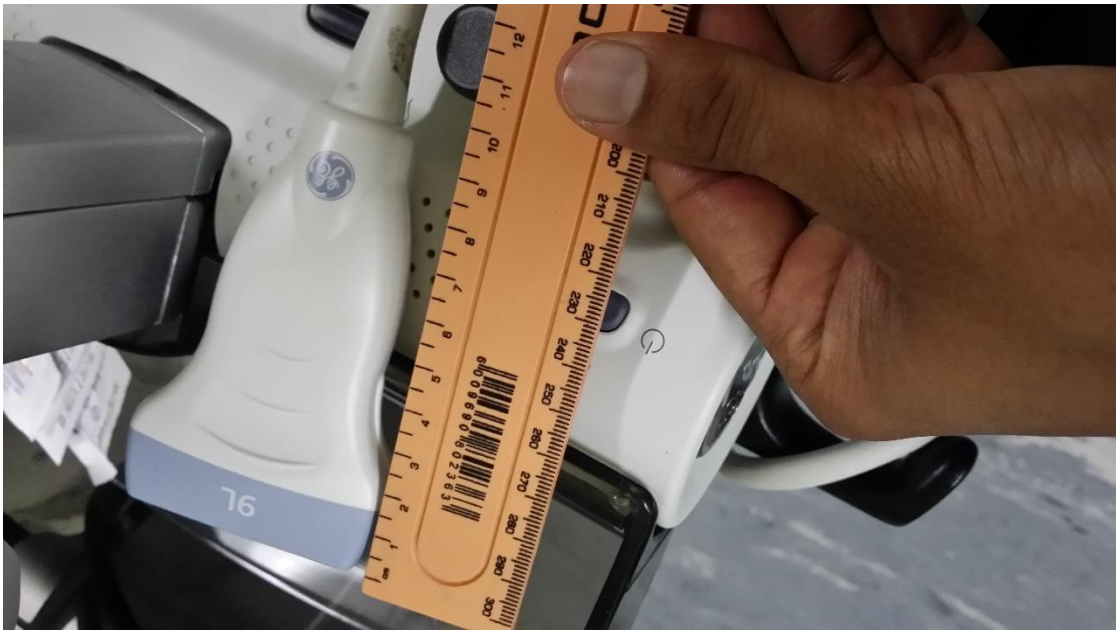

Figure 1. Wide band linear array probe from GE Health

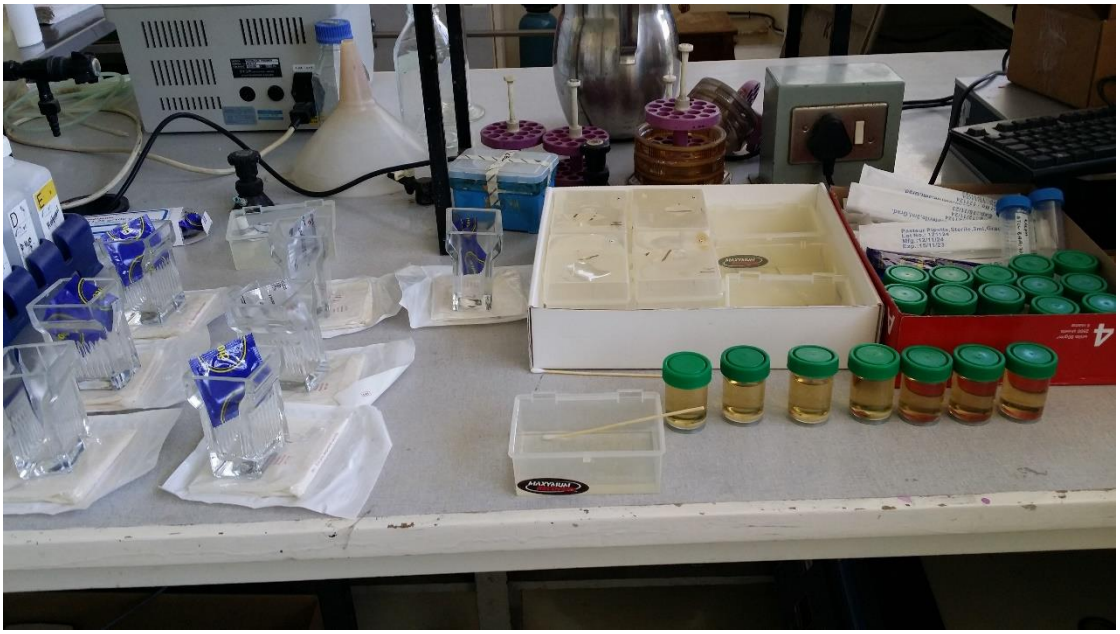

Figure 2. Pre-experiment setup. From left to right: Coplin jars with corresponding condom and sterile glove pack; Inoculated jelly in rectangular container; Unused nutrient broth in 20ml plastic flasks.

The bacterial challenge was prepared as follows. A 50g tube of sterile KY jelly (Johnson and Johnson, Johannesburg, South Africa) was decanted into an autoclaved plastic dish. This jelly was then inoculated with 5ml of *Staphylococcus aureus* and 5ml of *Klebsiella pneumoniae*, at a concentration of 0.5 McFarland (a) each. This resulted in a bacterial load in the range of 3 x 10^8 colony forming units in 50 grams of jelly + 10 ml of culture broth.

The ultrasound probe was simulated using rectangular coplin glass jars with the following dimensions: length 5.5cm, width 4cm and height 9cm. Each jar was inspected for sharp or

irregular edges. Thereafter, the bottom of each jar was dipped into the inoculated jelly. Using sterile technique as previously described for examining condom sterility, the condom was removed from the wrapper. Each condom was handled with a new set of sterile gloves and an assistant held the jar upside-down for placement of the condom. Each condom was stretched over the base of the jar to a height of 6 cm. Each jar was left to stand for twenty minutes. Thereafter each condom was carefully removed, to prevent sterility being compromised, and the distal part dipped into a container of nutrient broth for five seconds.

Figure 3 Coplin jars dressed with condom

The testing of the inoculated condom for bacterial translocation proceeded as follows: Particular emphasis was placed on removing the condom carefully and avoiding contamination. An assistant turned the jar upside-down. The condom was removed by placing two fingers inside the neck of the condom and sliding it off the jar. In this way, the outer

layer of the condom remained undisturbed. The distal part of the condoms was dipped into the nutrient broth.

After the five-second contact period, the condom was discarded and the 20ml container of nutrient broth was sealed and incubated for twenty-four hours. Contamination was measured as positive when the nutrient broth showed any turbidity. Thereafter, identification of the bacteria was to be performed.

7.4 Statistical methods and data analysis.

Sterility:

A sample size of 10 condoms was used. We expected the condoms not to have any bacterial contamination in its packaging.

Translocation:

Given the paucity of previous literature on the expected contamination rate and assuming that 50% of condoms would allow translocation, an original sample size calculation of one hundred condoms was based on 95% confidence interval widths of 10% above and below the original estimate. A clinically acceptable result would be that between 0-0.5% of condoms would allow any bacterial translocation.

Data were analysed using SAS version 9.3. Exact 95% confidence intervals were calculated for each phase. Results are presented as absolute and relative frequencies.

8. RESULTS

8.1 Examination of the sterility of the condoms prior to use

Of ten condoms, one (10%; 95% confidence intervals 0.3% - 45%) showed bacterial growth.

8.2 Examination of the condoms ability to prevent translocation of bacteria

The first batch consisted of thirty simulations. Of the thirty simulations, eighteen (60%; 95% confidence intervals 41% - 77%) showed bacterial translocation into the nutrient broth.

After thirty incubations, the experiment was aborted due to futility.

9. DISCUSSION

Sterility of condoms

The first leg of this project indicated that 10% of condoms were contaminated with bacteria. Of note, our acceptable value of contamination (0.5%) falls within the 95% confidence intervals. Therefore the study is underpowered to reject the hypothesis.

We had searched, prior to planning the study, for evidence favouring sterility of condoms, but the interrogation failed to reveal evidence confirming or disputing this contention. We therefore assumed that they were sterile. This may be a common and incorrect assumption held by many in the medical field. There have been claims that condoms have been used to have maintained sterility during a procedure..(18)

Condoms are most commonly made of latex rubber. Rubber gloves are also made of latex rubber and are sterilised by heating them to 109 degrees and under pressure (5 psi) for 20 minutes in a jacketed autoclave. An investigation into the sterilisation of rubber gloves revealed that standard methods

using temperatures in excess of 110 degrees Celsius caused vulcanisation and melting of the gloves which were then rendered useless.(22) The limited temperatures that the gloves can tolerate means that complete sterility cannot be guaranteed.(22) Similarly, condoms also do not conform to sterility required for medical procedures.

It stands to reason that condoms produced for contraception and prophylactic purposes are not required to be sterile. It appears that the manufacturers likely omit the sterilisation process as vulcanisation of condoms may compromise their intended purpose. There are, in fact, sterile condoms produced by medical companies such as De Royal Industries.(10)

Barrier protection offered by condoms

The results from our experimental model demonstrated that 60% (44% - 71%) of the condoms permitted transmission of bacteria. We therefore reject the null hypothesis stating that they were effective sterile barriers. This research suggests that, even if condoms were sterile, they are ineffective bacterial barriers.

Our ability to detect bacterial translocation validates our experimental model. Nonetheless, it seems counter intuitive that condoms would transmit bacteria and not the far smaller viruses. Common sexually transmitted disease (STD) pathogens include bacteria like *Treponema pallidum* and *Chlamydia*, and viruses like HIV. The particle size of the

Human Immunodeficiency virus is 0.12 microns, while mycoplasmas like *Chlamydia* are in the region of 0.44 microns. Typically bacteria range between 0.5 – 5 micron. Of note, sperm cells are approximately 40 micron.

It is accepted that condoms provide excellent barrier protection against spermatozoa,(26) but do condoms prevent passage of viruses at all? In an experimental study using physical conditions simulating coitus, fluorescence-marked microspheres comparable in size to the HIV virus was used to more accurately measure translocation of these particles across the condom barrier.(5) Twenty-nine of the 89 condoms tested allowed passage of the microspheres. This suggests that condoms are not infallible barriers to viruses.

Condoms are still the mainstay in prevention of spread (of HIV) in the sexually active population. One review suggested overall effectiveness of condoms in reducing the seroconversion rates of Human Immunodeficiency Virus (HIV) as 80%.(27) It is clear that the role of condoms in the prevention of STD's is important but complex. Unbiased testing of the role of condoms is inherently unethical. Factors other than simple barrier protection may play a role in the reduction of STDs.

A weakness of our study is that we did not include a control group to test the efficiency of commercially available sterile probe covers, this being the gold standard of ultrasound probe protection. Three different brands of probe-covers for oocyte

retrieval have been tested by filling the covers with water and testing for leakage (leakage being used as an indication of perforation). Perforation rates ranged from 25-81%, depending on the brand used in the study. However, high perforation rates on unused covers were also observed (25-81%). Therefore, despite being the gold standard, probe covers do not appear to be always effective.(13)

It is important to note that the dimensions of the jars used in our study differ from that of commonly used ultrasound probes. The jars used in our study had a circumference of 19 cm, as opposed to 12 cm for the wide band linear array vascular probe, or 7.62 cm for the trans-vaginal and trans-rectal probes. Commercial probe sheathes are provided in a range of sizes to fit the various probe sizes. In comparison, condoms are only available in one size. It might be that overstretch of the condoms compromised the results.

However, we intended to investigate the worst-case scenario with significant stretch and bacterial load. It would have been helpful if smaller “probes” were also examined, but that may have provided false negative results.

A similar study during trans-rectal prostate biopsies (18) also tested for leaks before and after the procedure by filling the condoms with water. This study demonstrated a 9% condom perforation rate when examined after the procedure.

We assumed that commercially available probe covers would provide perfect protection against bacterial translocation. However, the aforementioned studies suggest this to be an unrealistic objective.

Our study was terminated prematurely due to futility. Another aspect of the study that was abandoned was the idea of selective culturing. Specific organisms were selected for the inoculation, the rationale being that if either of these organisms were cultured, it could be assumed that translocation through the condom had occurred. While extreme care was taken to maintaining an aseptic protocol similar to that employed in an operating theatre, a possible lapse in sterility at opening the condom cannot be excluded. The removal of the stretched condoms from the probe model was also a concern, but was performed extremely carefully and it is unlikely that this was the cause of contamination. The high rate of bacterial growth meant that the technique was not suitable no matter what the cause of the contamination. We therefore did not continue with selective culturing.

The conditions for these experiments were chosen to not only simulate standard clinical conditions, but to simulate an extreme case scenario in terms of stretch of the condom and bacterial load. Therefore a relatively large ultrasound probe model was chosen and a relatively high bacterial load in the jelly was used. Circumference size of the model employed was 19cm compared to 12cm for the standard vascular ultrasound probe (GE Health), with most other probes having smaller circumferences.

The condoms were obtained from state hospital condom dispensers. A majority of South Africans would have access to identical free condoms at any state facility in South Africa. This makes our attempt at simulating the clinical scenario more authentic. External factors such as exposure to sunlight cannot be ruled out. We did, however, ensure that expiry dates were adhered to and that the condom package was intact and airtight before experimental use.

A better way to eliminate contamination from the experimental control would have been to expose the condoms to the culture broth without removing them from the probe model first. In this study it was not possible, as the dressed probe model did not fit into the incubation flasks readily available for culture.

The study needs to be repeated to further explore alternative draping of probes for sterile procedures. Future studies should be conducted using a control group of commercially available sheaths: This approach will increase confidence in the results. Furthermore, various sizes of probe models coinciding better with the actual probe sizes should be used to ascertain whether the stretch of the condom compromised the results. It seems impractical to use actual probes in this experiment, they are extremely expensive and the risk of contamination is unacceptably high. Advances in technology make the use of 3D printers an attractive alternative. One could specific render probe models corresponding to the actual size of commercially available probes.

The ideas put forward in this study revolves around the experimental model we chose. It is unknown whether manufacturer assured sterile condoms may yield better results on a smaller probe model with a lower bacterial challenge. We close the discussion with the recommendation that further studies be conducted to address the above perplexities. Furthermore, it would be interesting to test the use of sterile, plastic condoms or even “femidoms” for their efficiency to prevent bacterial translocation.

10. CONCLUSION

The results of the study suggest that the use of condoms, as a sterile ultrasound barrier, may not prevent translocation of bacteria in clinical practice. A number of factors may influence the effectiveness of condoms, such as the probe head size, bacterial load and manufacturing quality of the condom. The latter relates to manufacturing standards, adherence to sterilisation protocols and whether the condom is within expiration date. Further studies as suggested in the discussion are needed to compare the use of condoms to commercially available probe covers in sterile ultrasound investigations.

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12. ADDENDUM

a) McFarland standard: In microbiology, McFarland standards are used as a reference to adjust the turbidity of bacterial suspensions so that the number of bacteria will be within a given range to standardize microbial testing. 0.5 McFarland equates to 1.5 x 10^8 CFU/ml. (CFU is colony forming units)

b) Nutrient broth: Media used by microbiologists containing elements essential for bacterial growth. These include: carbon source (glucose), water. Salts for bacterial growth, nitrogen source (e.g. beef extract)