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Research Article

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ABSTRACT

Background: Over the years, there has been frequent concern on the use of male latex condoms because of its dual functions of preventing unintended pregnancy and sexually transmitted infections in the society. However, their use is limited in part by questions about their performance which may be influenced by many factors including its production qualities. In Nigeria, all condoms in use are imported and as such greater effort needs to be applied in quality assurance of the numerous sources.

Objectives: To estimate the rate of condom leakage among the available male latex condoms in Nigerian market and compare it with results published from other countries.

Methods: A water leak hang test on a random sample of available brands of male latex condom in Nigerian health shops was done. Six commonly available male latex condoms were selected and labeled A, A, B, C, D & E. Fifty (50mls) of water was instilled into the unused condom and sequentially hung up for gravity effect. The primary outcome measure was the leakage of water in the condom within 2 minutes. Analysis was done using Epi-info 2008 version 5.3.1.

Results: A total of 495 male latex condoms were used in the trial. All the condoms are expected to expire in at least 24 months. Of this number, 25 condoms leaked water, giving the estimated condom leakage rate of 5.05% in Nnewi South-East Nigeria.

Conclusion: The leakage rate for male latex condom was very high in Nnewi, Nigeria based on this estimate. This poses a reproductive/public health concern with respect to prevention of unintended pregnancy and other preventable Sexually Transmitted Infections (STIs). Condom studies are therefore a high priority in Nigeria given the HIV/AIDS, hepatitis and sexually transmitted disease high prevalence.

KEY WORDS: Latex condom, leakage, Unintended Pregnancy.

INTRODUCTION

Condom usage has always been a major area of research in sexual health, health promotion, sexual medicine, and sex education. This is particularly so in Nigeria where the transmission rate of HIV and Hepatitis is yet to stabilize. The high rate of unintended pregnancy as well is a social and health problem. Generally people have often considered brand, texture and occasionally flavour when shopping for condoms, but few think about quality. Public health modulators however, do consider quality from time to time.

Water leakage tests have been used by the Food and Drug Administration (FDA) to evaluate the barrier quality of condoms since the 1950s. A number of engineering and analytical centers have been actively researching on the efficacy of water leak test methods for various barrier contraceptives. However to make sure that condoms are safe and protective as intended, government agencies of various countries test condoms that are pushed into the market for use very often.
A number of models exist for testing of condoms\textsuperscript{1}. The most true model of condom performance is sex itself and so humans are the most ideal models\textsuperscript{3}. Humans as models have several drawbacks. While using humans, they are not convenient and there are a lot of ethical issues while adhering to high standards of uniformity\textsuperscript{3}. An alternative to trained human “sex technicians” is the “empty-condom” tests. These include electrical conductance test, water leak test, tensile test, and airburst test\textsuperscript{3,5,6}.

Water leak test involves filling a condom with 10 ounces of water and looking for leaks\textsuperscript{3,7,8}. The water test can detect holes only as small as 5 mm, but this sized hole is many times the size of sexually-transmitted viruses and even of the bacterium \textit{Chlamydia}\textsuperscript{1,3}. Regardless of which specific test is used, condom testing involves taking a sample of several condoms from a batch and after tests, calculating the fraction that pass the test.

A supply of condoms of sustainable quality will no doubt continue to be an issue of concern in public health, reproductive and sexual health.

Although the latex material used in condom has the advantages of being produced in thin sheets, and it can stretch greatly without breaking, it is profoundly sensitive to various environmental conditions. Even temperatures as high as body temperature degrade it, albeit slowly, and oils such as vegetable oil and baby oil, degrade it rapidly\textsuperscript{3,9,10}. So, even if condoms meet reasonable standards in the factory, they may fail under a wide variety of conditions encountered in “the field.”

Against this supposedly backdrop, this study aims to estimate the rate of condom leakage among the available male latex condoms in Nigerian market.

**METHODS**

A randomized trial was conducted in June 2011 at Chimex Specialist Hospital, Nnewi, South-east Nigeria using six available brands of male latex condoms in Nigeria market (which were labeled imported from countries A\textsubscript{1}, A\textsubscript{2}, B, C, D, E, manufacturers).

Each condom was randomly selected and subsequently removed from its original packaging and unrolled followed by instillation of 50 mls of water into the latex condoms and sequentially hanging it under gravity by means of baby towel clips, sharp objects were avoided and absorbents towel or paper used to wipe off exteriors. It was then observed for 2 minutes for evidence of leakage of water (water leak hang test). The observation for leakage of water was augmented by rolling an adsorbent paper over the base of the condom and observing for presence of water.

All the condoms were contoured in shape, had a nominal length of 180 mm, a nominal width of 52 mm and a nominal thickness of 0.07 mm. They were pre-packaged in cellophane pouches. We included only the condoms that had at least 24 months before attaining its expiry date, were used for the study.

The primary outcome to be measured was the leakage of water in the condom within 2 minutes of hanging. Analysis was done using Epi-info 2008 version 5.3.1.
RESULTS

In this trial, 495 different male latex condoms were used. Of this number, 25 condoms had leakage of water. This gave a condom leakage rate of 5.05%. The details are as shown in the table attached.

Table 1: Condoms used and their respective leakage rate

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>No Leaking</th>
<th>No non leaking</th>
<th>Expiring Date</th>
<th>Leakage rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1</td>
<td>2</td>
<td>70</td>
<td>2014</td>
<td>2.86</td>
</tr>
<tr>
<td>B</td>
<td>1</td>
<td>99</td>
<td>2013</td>
<td>1.01</td>
</tr>
<tr>
<td>C</td>
<td>13</td>
<td>131</td>
<td>2013</td>
<td>9.92</td>
</tr>
<tr>
<td>D</td>
<td>5</td>
<td>33</td>
<td>2013</td>
<td>15.15</td>
</tr>
<tr>
<td>E</td>
<td>2</td>
<td>65</td>
<td>2013</td>
<td>3.08</td>
</tr>
<tr>
<td>A11</td>
<td>2</td>
<td>72</td>
<td>2014</td>
<td>2.78</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>25</strong></td>
<td><strong>470</strong></td>
<td><strong>-</strong></td>
<td><strong>5.05</strong></td>
</tr>
</tbody>
</table>

DISCUSSION

The purchase of poor-quality condoms will adversely affect every aspect of condom promotion and programming. Not only that it is a waste of limited economic resources, but it also devalues the credibility of the one inexpensive device that has been proven to help prevent the transmission of HIV/AIDS and unintended pregnancy\(^1\),\(^2\). Surprisingly, in this study, the male latex condom leakage rate is very high (5.05%) and does not compare favorably with the accepted ACOG committee opinion of 0.4%\(^2\). This finding poses a very serious reproductive/public health concern with respect to prevention of unintended pregnancy and prevention of mother to child transmission (PMTCT) of HIV/AIDS\(^1\),\(^2\). A large body of research in the United States has shown that rates of leakage, caused by fault in the condom itself, are less than 2 condoms out of every 100 condoms\(^3\),\(^12\). Additionally, in the US, a batch of condoms cannot be marketed if 5 or more condoms per 1000 fail the test\(^3\).\(^4\).

Different countries have different regulatory agencies for condom sale. In the United States, the Food and Drug Administration (FDA) regulates condoms to ensure their safety and sustainable good quality\(^9\),\(^10\). WHO guidelines set out a range of test requirements, which are necessary for ensuring the quality of each lot of condoms purchased\(^12\),\(^13\). Based on international standards set out by the International Standard Organization (ISO), the examples of the tests used by condom manufacturers include the 'water leak test', which reveals any holes in a condom, and the 'air burst test' or 'tensile test', which shows whether a condom is likely to leak during use. Additionally, before the condoms are made available for public use, a random sample of them are tested for leaks and other imperfections to ensure that national and international standards are met\(^12\),\(^13\). If any of the condoms fail the test, the whole batch which can contain over 400,000 condoms are discarded\(^12\),\(^13\).

A water leak test as conducted in this study may not be a true reflection of the performance of the condoms when compared with the use of human models\(^13\). Such comparative studies conducted in the past also noted this difference between quality and human models tests\(^12\),\(^14\). While testing for condom leakage in the regulatory laboratories, or in the factories as part of production screening or quality assurance efforts, is a major tool for ensuring condom reliability, performance quality in human still remains the ideal assurance test.

Additionally, condoms are very sensitive to various environmental conditions, high body temperature can degrade it, albeit slowly\(^1\),\(^7\),\(^8\). So even if condoms meet reasonable standards with the manufacturers, they may still fail under a wide array of conditions. However, the finding was important and reportable since all the condoms used in this study had an expiry date of more than 24 months and were all imported.

In conclusion, the male latex condom water leakage rate in Nnewi South East Nigeria is very high (5.05%) and does not compare favorably with the accepted ACOG committee opinion of 0.4%. Condom quality studies are therefore a high priority in Nigeria given the high prevalence of HIV/AIDS and other sexually transmitted diseases and high incidence of unsafe abortion consequent upon high prevalence of unwanted pregnancy. More quantitative and alternative researches are however needed, both to validate these findings and to identify indicators that may cause condoms to leak. It is therefore important for policy-makers, programme managers, bulk procurement agencies, social marketing programmes, logistic/procurement officers and national regulatory authorities to know how to apply the essential elements of condom quality assurance to guarantee that a quality product is available for purchase by the end user.
DECLARATION OF INTEREST

The authors report no conflicts of interest. The authors alone are responsible for the contents and writing of the paper.

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