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Review Article

Sanitary Surveillance of Male Condoms in the City of Rio De Janeiro during the Covid 19 Pandemic

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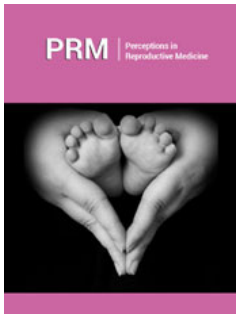

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Abstract

Background: The increase in the incidence of Sexually Transmitted Infections (STIs) represents an important public health problem. The natural latex male condom is a resource available to men and women that fulfills a dual protective function. In Brazil, male condoms are compulsorily certified. Although the certification process evaluates the manufacturing process in detail until the final product, it does not address commercialization issues, as it is a function of the sanitary surveillance.

Methods: Two different brands of male condoms, purchased in the Rio de Janeiro city trade (Sample A) (Sample B) were evaluated. The quality control of the male condom involves one important insufflation test, which evaluates the resistance determining the volumetric capacity and the rupture pressure. For the insufflation test, we tested 200 units per brand, according to the criteria established in the Resolution of the National Agency of Sanitary Surveillance nº. RDC 554/2021 that allows up to seven nonconforming units.

Results and Conclusion: Both the two brands met the criteria established in the Resolution of the National Health Surveillance Agency no. RDC 554/2021 for the inflation test, which allows up to seven nonconforming units, however, we found nonconformities in both. We conclude that, in addition to certification, there is a need to monitor this product in view of the sanitary risk observed

Keywords: Male condoms; Public health; Sanitary surveillance

Abbreviations: STIs: Sexually Transmitted Infections; SBD: Brazilian Society of Dermatology; WHO: World Health Organization; MPT: Multi-Purpose Prevention Technology; AQL: Acceptable Quality Level

Introduction

Background of the study

The World Health Organization (WHO) estimates 1 million new cases of curable sexually transmitted infections (STIs) among people aged 15 to 49 worldwide every day. These numbers can exceed 376 million annual cases when referring to the four most common types of STIs. These data demonstrate the challenge for public health, since these infections can generate serious consequences, in addition, many infected individuals do not present any of the typical symptoms, increasing the risks [1]. When we talk about STI prevention, we list the need to use condoms, a method that is known to be effective, cheap and accessible to the population [1]. Natural latex male condoms are a resource available to both men and women that serve a dual protective function. They are inexpensive, easy to manufacture and are easily distributed globally, even in resource-poor settings, through numerous and well-developed distribution channels, with the exception of allergic people, they have no contraindications [2]. One of the main measures to prevent Sars-CoV-2 is physical distancing, which can impact people's sexual experiences [3]. However, according to Unaids, a program of the United Nations (UN), key

populations for HIV would be equally vulnerable to COVID-19 and the new pandemic has impacted on global strategies for prevention and care in HIV/AIDS [4].

As a result of the social isolation imposed by the Covid-19 pandemic, patients infected with the disease stopped seeking health services when they manifested symptoms. According to the Ministry of health of the Brazilian Government, between January and June 2020, 49,000 cases of syphilis were recorded, transmitted mainly through sexual contact without the use of condoms [5]. From 2010 to 2020, Brazil recorded 783,000 cases of the disease, which continues to grow significantly, according to the Brazilian Society of Dermatology (SBD). Syphilis affects mainly the male population, which represents 59.8% of cases. Women, in turn, account for 40.2%, but they deserve special attention, as many reveal symptoms during pregnancy, increasing the risk of contamination of newborns [6]. Today, nearly 30 billion condoms are sold worldwide each year. Since 1990, an estimated 45 million HIV infections have been prevented by using condoms, according to Unaids. However, over 1 million STIs are still contracted every day, according to the WHO and around 80 million pregnancies a year are unintended, which many public health experts insist the male condom still plays a big role in. In preventing the spread of disease and planning family [7].

The WHO warns that if condoms are designed correctly, with adequate elasticity and strength, uniform and without holes, they significantly reduce the risk of transmission of pathogens during sexual intercourse, being considered an ideal example of multifunctional prevention technology (MPT - Multi-Purpose Prevention Technology). However, they are not perfect, they are made from latex and can vary by lot and differences in manufacturing technology, which can result in considerable variation in their quality. The only practical method for assessing the quality of condoms is the characterization of a representative sample from a batch or series of batches. This is because natural rubber condoms are mass-produced items, manufactured in grand-volume production batches. Thus, individual variations in product quality inevitably occur. Therefore, it is foreseeable that there is a proportion of condoms from a production batch that does not meet the requirements established in the product quality standards. In addition, the tests used for product evaluation are destructive tests [7]. In Brazil, male condoms, like other products that may have some kind of impact on health, consumer safety or the environment, are compulsorily certified. However, the certification process, although it evaluates in detail the production and the product at the end of manufacture, does not address the issue of commercialization in the various establishments as they are considered typical issues of sanitary surveillance.

The quality of condoms available in Brazil is under the jurisdiction of the Brazilian Sanitary Surveillance Agency (ANVISA) under the Brazilian Ministry of Health. The Brazilian law-Brazilian National Health Oversight Agency Resolution no. 554/2021, based on the ISO 4074 standards establishes the technical regulation for certification of male condoms of natural rubber latex specifies that condoms must be certified under the Brazilian certification system in accordance with the requirements of the indicated technical regulations before its sale or free distribution to consumers [8-10]. The presence of poor-quality condoms on the market represents a serious challenge in the fight against STIs. The lack of quality of this product affects the popular perception of the value of the condom, which, in turn, can have a significant impact on public health. Therefore, they can harm not only the health of users, but also the reputation of agencies or the national agency that provides condoms.

Methods

Two brands of male condoms, anonymized by marking with letters, purchased in the Rio de Janeiro city trade (sample A) and (sample B) were evaluated. The analytical tests carried out on the brands were the physical insufflation test. The physical insufflation test in all regulations, the bursting volume requirement is linked to the nominal condom width, measured at 75±5mm from the closed end, excluding the reservoir tip. Bursting volume and bursting pressure were measured in accordance with standards established by the Brazilian National Health Oversight Agency Resolution no RDC 554/2021, using an four-head automated inflation system (Enersol™, Sydney, Australia). For this analysis, we used the ISO 2859 single sampling plan, with a normal inspection regime, at inspection level I (Acceptable Quality Level (AQL)=1.5, less than 1.5% of units defective). The number of units assessed was 200 per lot, and the acceptance criteria reject the lot if at least eight nonconforming units were identified. During the insufation test, the condom is inflated like a balloon, stretching the latex film until its rupture, thereby indicating its maximum resistance. The inflation system is accompanied by software that logs the pressure and volume at bursting. The compressed air that supplies the system is generated by a dry, oil-free air compressor. The flow of compressed air was set at 24–30dm3min-1, as defined in the standards. For each condom, the bursting pressure (1kPa=N force applied uniformly over an area of 1m2) and bursting volume (in dm3) were logged via the Inflation 3 software [9,11-13].

Results

For physical tests, (Table 1) presents AQL, amount of sample teste and the criteria established in accordance with RDC 554/2021. (Figure 1 & 2) represent the insufflation tests performed on samples A and B, respectively. The variability for burst pressure and volume shows that the units are not uniform. However, the distribution extends to the left for both pressure and volume, characterizing a non-normal distribution contaminated by outliers, but within the compliance area. However, both samples presented volume and pressure values below the established values. Found three nonconformities in volume and one in pressure for sample A and one nonconformity in volume for sample B. By the characteristics of the graphs, we noticed a variability in the of the samples studied. This can be explained by the fact that it is a mass-produced product, influenced by the properties of the latex film, the type of storage of the product to its use among others, which highlights the importance of post-market monitoring beyond certification.

Table 1: Criteria established by RDC 554/2021 for physical tests for male condoms.

Physical Test	Acceptable quality level (AQL)	Amount of Sample Tested	Maximum Acceptable Non-Conforming Units
Length, width, thickness	4,0	13	2
Holes	0.25	315	3
Primary packaging integrity	2.5	20	2
Bursting volume and bursting pressure	1.5	200	7
Label and secondary packaging	1	13	1

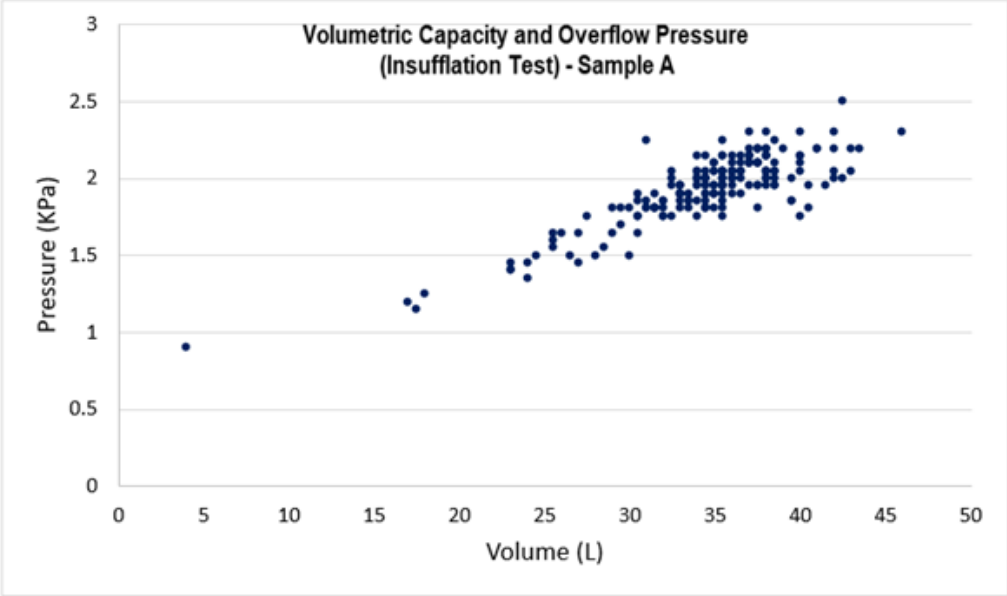

Figure 1: Insufflation test-sample A.

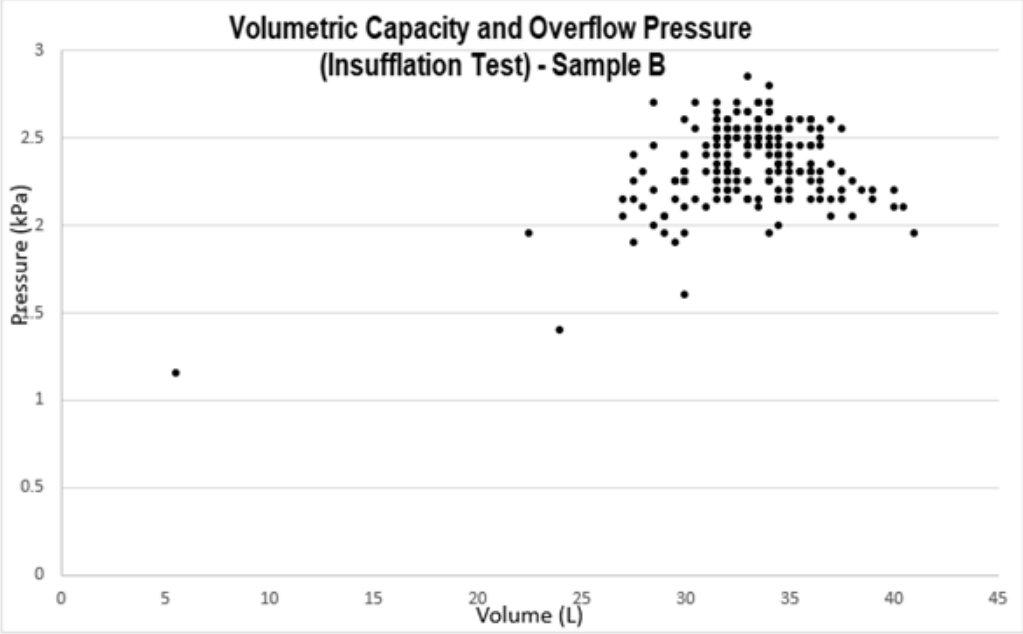

Figure 2: Insufflation test-Sample B.

Conclusion

Inflation tests are internationally standardized and have great importance in the factor of evaluation of the product. According to World Health Organization specifications and condom quality standards, insufflation tests, integrity of the primary packaging and the amount of lubricant together are useful for evaluating condom performance. These properties are the best indicators of product performance. The insufflation tests measures both properties and is performed on most of the product with proven sensitivity in the relationship between these parameters and the degradation of the product. The results found, although the samples are within the limits of compliance established by the standards, illustrate the importance of performing quality analyzes in a broad way, since, in most cases, the manufacturing batch indicates non-compliance in one or more tests, allowing to indicate the need, in addition to certification, of the importance of the actions of the National Health Surveillance System in the systematic and active monitoring of male condoms available on the market.

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