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ARTIGO

Sanitary Surveillance of natural latex male condoms commercialized in Rio de Janeiro, Brazil: analysis of volumetric capacity and burst pressure

Vigilância Sanitária de preservativos masculinos de látex natural comercializados na cidade do Rio de Janeiro, Brasil: análise da capacidade volumétrica e pressão de estouro

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ABSTRACT

Objective: The increased importance of using condoms to protect men and women from sexually transmitted diseases and HIV infection has sensitized health authorities to condom quality. However, the resolution for product certification is also used for sanitary evaluation. Although the certification process evaluates in detail manufacturing the production and final product, it does not address marketing in establishments such as pharmacies, drugstores, and supermarkets – a typical issue considered for Sanitary Surveillance. Quality control of male condoms involves the important insufflation test, which evaluates resistance by determining volumetric capacity and bursting pressure. **Method:** We evaluated 20 brands of male condoms, domestic and imported, from eight manufacturers, marketed in Rio de Janeiro, Brazil. We tested 200 units per brand. **Results:** All brands met the criteria established in the Brazilian National Health Oversight Agency Resolution no. RDC 62/2008, which allows up to eight nonconforming units. However, nonconforming units were identified in 12 of the brands tested. **Conclusion:** From the perspective of Sanitary Surveillance, even a single nonconforming unit has serious implications for public health.

KEYWORDS: Male Condoms; Public Health; Sanitary Surveillance**RESUMO**

Objetivo: O aumento da importância do uso do preservativo como uma ferramenta para proteger homens e mulheres contra as doenças sexualmente transmissíveis e infecção pelo HIV sensibilizou as autoridades de saúde em relação à qualidade de preservativos. Contudo, a mesma Resolução utilizada para certificação do produto é usada para avaliação sanitária. Muito embora, o processo de certificação avalie com detalhes a produção e o produto ao final da fabricação, não aborda a questão da comercialização nos diversos estabelecimentos como farmácias, drogarias, supermercados, por ser considerada uma questão típica de Vigilância Sanitária. Um dos principais ensaios para o controle de qualidade do preservativo masculino é o teste de insuflação, que avalia a resistência por meio da determinação da capacidade volumétrica e da pressão de estouro. **Método:** Foram avaliadas 20 marcas de preservativos masculinos, nacionais e importados, de oito fabricantes, comercializados na cidade do Rio de Janeiro, Brasil. Foram testados 200 unidades de preservativos por marca. **Resultados:** Todas as marcas atenderam aos critérios estabelecidos na Resolução da Diretoria Colegiada da Agência Nacional de Vigilância Sanitária, Resolução nº RDC 62/2008, que permite até oito unidades não-conformes. No entanto, em 12 marcas foram observadas unidades não conformes. **Conclusão:** A partir de uma perspectiva da Vigilância Sanitária, uma unidade não conforme tem sérias implicações para a saúde pública.

PALAVRAS-CHAVE: Preservativos Masculinos; Saúde Pública; Vigilância Sanitária



Introduction

The male condom is defined as a wrap of waterproof material designed to cover the penis and prevent exchange of body fluids during sexual intercourse. The basic condom model is a film of natural rubber latex in the shape of a cylindrical tube, with the sheath thicker at the open end. At the closed end, the condom is rounded and usually has a reservoir tip designed to store semen. If used correctly and consistently by conscientious users, natural rubber latex condoms have a number of advantages specific to the raw material and the design, thus providing satisfactory contraception and preventing sexually transmitted diseases (STDs) without side effects. Male condoms in small packages can be stored discreetly, are inexpensive, are easily and readily used, and have been available for consumption for more than half a century, making them widely known and well accepted.

At the end of the 1980s, faced with the HIV epidemic's potential impact, the World Health Organization (WHO) implemented its Global Program on Acquired Immunodeficiency Syndrome (AIDS). That program recognized the preventive significance of male condoms, and the WHO established specifications to ensure that not only the WHO, but also other buyers would be able to acquire good quality condoms to prevent HIV infection¹.

Since the beginning of the 1990s, the Brazilian National STD/AIDS Program, which is today the Department of STD, AIDS and Viral Hepatitis of the Ministry of Health, recognized the distribution of condoms made of natural rubber latex as the centerpiece of governmental policy for preventing AIDS and other STDs².

One objective of the Action Plan and Annual Goals of the Brazilian STD/AIDS Program Strategic Plan, implemented in 2005³, was the Brazilian government's acquisition of one billion condoms. This strategy aligned with the guidelines of major international organizations, the WHO, the Joint United Nations Program on HIV/AIDS, and the United Nations Population Fund, which jointly reported, in July 2004, that "the male latex condom is the single most efficient available technology to reduce the sexual transmission of HIV and other sexually transmitted infections" and that "condoms should be readily and universally available, for free or at low cost, and promoted in ways that help overcome social and personal obstacles in their use"⁴.

The quality of condoms available in Brazil has been widely debated since 1987, when condoms were included in the category of pharmaceuticals remaining under the jurisdiction of the *Agência Nacional de Vigilância Sanitária* (ANVISA, Brazilian Sanitary Surveillance Agency) of the Ministry of Health. At various times, depending on the agency in charge of testing and on the samples and lots selected, condoms available to the population were shown to fall below the quality standards required for safe and effective use, either as a contraceptive device or as a mechanical barrier to the transmission of STDs and HIV⁵.

In Brazil, male condoms, like other products that can impact health, consumer safety, or the environment, must have

compulsory certificates; i.e., they cannot be marketed or distributed without having received a seal of conformity, which certifies that a product meets the minimum quality standards established to predict safety and effectiveness. Condom samples undergo tests that include measurement of their dimensions (length, width, and thickness), bursting volume and bursting pressure, as well as inspection to detect the presence of holes or other defects. Accuracy in labeling and integrity of the packaging are also assessed. Sampling procedures in Brazil accord with ISO 2859⁶ and ANVISA Board Resolution no. RDC 62/2008, for lot sizes of 150,001-500,000⁷. The sampling procedures for inspection by attributes (ISO 2859) constitute a recognized standard that specifies a sampling inspection system, indexed in terms of the acceptable quality level (AQL). The objective is to induce suppliers to maintain a level of quality at least equal to the expected by the customer. The ISO 2859 sampling procedures for inspection by attributes define the acceptance criteria, the level of inspection (I, II or III), and the inspection regime based on the size of the lot.

The insufflation test (of bursting volume and pressure) has been used as an indicator of a condom's resistance. This test's main advantage is that it allows a nearly complete assessment; it is sensitive enough to localize flaws in the film and makes it possible to correlate poor test performance with product aging/degradation and the rate of breakage in use. For this analysis, we used the ISO 2859 single sampling plan, with a normal inspection regime, at inspection level I (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, as established in RDC 62/2008 for Brazil and throughout the Common Market of the Southern Cone. It is noteworthy that, in accordance with Appendix F of RDC 62/2008, condom samples manufactured within the last twelve months are artificially aged in a kiln prior to the insufflation test to determine the sample's stability and to ensure product quality until the lot's established expiration date⁹.

As part of a strategy to increase access to and use of condoms with the desired quality, Brazil has established and standardized quality and control. As a result of implementing integrated and comprehensive actions, the *per capita* use of male condoms has increased. To complement its "social" and commercial marketing, free distribution remains important, especially among the poorest inhabitants. However, the "social marketing" of condoms in Brazil boosted competition and facilitated market expansion. This was particularly relevant in Brazil, where there is a well-established middle class and the overall condom market was underdeveloped in the early 1990s⁸. In Brazil, "social marketing" of condoms targets lower socioeconomic classes, whereas its commercial marketing targets the middle and upper classes. The main result of "social marketing" was increased sales for all social classes; this also yielded increasing profits and jobs in the private sector



(manufacturers and importers of male condoms). Given that over the years family planning programs have favored highly efficient contraceptive methods, such as the pill and sterilization, the significant increase in condom sales in Brazil as a result of the AIDS epidemic has made condom use an important preventive method^{8,9}.

The Brazilian government's plan evinced efforts to integrate STD/AIDS prevention into the public health care network resulting from the decentralization of the *Brazilian Unified Health Care System* (SUS). The national program DST/AIDS has sponsored descriptive studies and developed systems for monitoring the management of programmed actions, as well as the populace's attitudes, behaviors, and practices. Nevertheless, studies evaluating prevention strategies and practices are extremely rare^{10,11,12}.

Although use of the male condom, the principal prevention method for sexual transmission of HIV, is considered simple and inexpensive, it requires sophisticated oversight. Condoms' importance is perceived as disease prevention and contraception, but no specific work in sanitary product evaluation exists because monitoring is limited in all existing standards, certification, and quality assurance. The National Institute of Quality Control in Health (INCQS) is a unit of the Oswaldo Cruz Foundation (Fiocruz), which operates in the areas of teaching, research, and laboratory technologies for quality control of raw materials, products, environments, and services subject to sanitary surveillance. INCQS functions as a national benchmark for scientific and technological issues related to quality control of products, environments, and services related to health surveillance. Today, it is considered the only Public Health Laboratory performing this work. Therefore, this study aimed to evaluate the quality of condoms sold in Rio de Janeiro, Brazil, by testing bursting volume and pressure.

Material and Methods

In all regulations, the bursting volume requirement is linked to the nominal condom width, measured at 75 ± 5 mm from the closed end, excluding the reservoir tip. Table 1 shows the relationship between nominal width condoms and the criteria established in National Health Oversight Agency Resolution – RDC 62/2008 for bursting volume.

In this research, we evaluated 200 units each of 20 different brands of male condoms from eight different manufacturers – a total of 4,000 units.

Bursting volume and bursting pressure were measured in accordance with RDC 62/2008, using an eight-head automated inflation system (Enersol™, Sydney, Australia). During the insufflation 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

Table 1. Relationship between nominal width condoms and the criteria for bursting volume.

Nominal Width (mm)	Volume (dm ³)
< 50	≥ 16
≥ 50 < 56	≥ 18
≥ 56	≥ 22

at 24–30 dm³ min⁻¹, as defined in the standards. For each condom, the bursting pressure (1 kPa = 1 N force applied uniformly over an area of 1 m²) and bursting volume (in dm³) were logged via the EInflation3 software^a.

Results and Discussion

Historically, the insufflation test has indicated condom strength by measuring the pressure and volume of overflow. The test's main advantages are almost complete evaluation of the artifact: sensitivity to faults in the film, the possibility of correlating low test performance with condom degradation and aging, and the rate of breakage in use. Figure graphically presents insufflation test results for a sample.

Among the 20 brands analyzed (one lot per brand), we identified nonconforming units, in terms of bursting volume or bursting pressure, in 13 brands (Table 2). One brand was specially formulated for those allergic to natural rubber latex (D15). Although that brand was evaluated using the same criteria as for the natural rubber latex condoms, we disregarded the results because the existing legislation (RDC 62/2008) is specific to natural rubber latex condoms. Table 1 shows that there were nonconforming units in the lots of twelve brands of natural rubber latex condoms. However, in every instance, the number of nonconforming units was less than the eight required for rejection of the lot on the basis of the RDC 62/2008 criteria.

Although all brands were satisfactory regarding the RDC 62/2008 criteria, the identification of nonconforming units in 12 of the 20 brands analyzed is relevant.

The results presented here are significant, and additional efforts will be needed to continue expanding sustainable access to condoms as a basic strategy for preventing sexual transmission of HIV and STDs in Brazil. Based on these results and in view of the potential harm to public health, we suggest that this legislation (RDC 62/2008) actually hinders ANVISA's activities. There is a need to establish appropriate and specific criteria for quality assessment of condoms within ANVISA, which can effectively collaborate with the national program of DST/AIDS in ensuring the efficacy and quality of condoms sold or distributed to the population, thereby safeguarding public health.

So the primary focus of the *Brazilian Unified Health Care System* (SUS) guidelines for decentralization is comprehensiveness of care, with prevention and community participation

^a Enersol Consulting Engineers. EInflation3. Sidney; 2000



Table 2. Results of insufflation tests of 20 brands of condoms, showing the numbers of nonconforming units, in terms of bursting pressure and bursting volume, as defined in Board Resolution nº RDC 62/2008 of the Brazilian National Health Oversight Agency.

Brand/ Lot	No. Units Tested	No. of Nonconforming Units		Average		Standard Deviation	
		P	V	P	V	P	V
		(kPa)	(dm ³)	(kPa)	(L)	(kPa)	(L)
A1	200	0	0	2.35	32.91	0.19	2.40
D2	200	1	2	2.14	34.20	0.30	4.50
C3	200	0	0	1.74	32.32	0.20	2.55
A4	200	0	0	1.72	30.80	0.14	2.90
F5	200	0	3	2.02	32.74	0.30	4.33
G6	200	1	0	1.70	55.56	0.15	4.90
H7	200	0	1	1.80	29.60	0.15	2.60
H8	200	0	0	1.80	32.07	0.13	3.60
B9	200	0	2	2.30	32.00	2.51	3.80
D10	200	0	0	2.31	29.95	0.14	2.04
D11	200	1	5	1.90	31.04	2.70	4.22
B12	200	0	1	2.20	27.50	1.84	2.80
E13	200	2	2	1.85	34.14	0.14	3.61
E14	200	0	0	2.07	37.80	0.10	2.20
D15 ^a	200	2	2	2.22	40.71	0.23	4.81
A16	200	0	1	2.19	29.41	0.24	3.14
A17	200	2	1	1.90	33.53	0.20	3.50
A18	200	0	4	2.30	29.80	0.30	3.50
A19	200	0	2	2.08	29.45	0.20	2.80
G20	200	0	0	1.60	31.80	0.13	2.60

Notes: P = bursting pressure; V = bursting volume.

^aHypoallergenic brand – not tested, because the legislation does not apply.

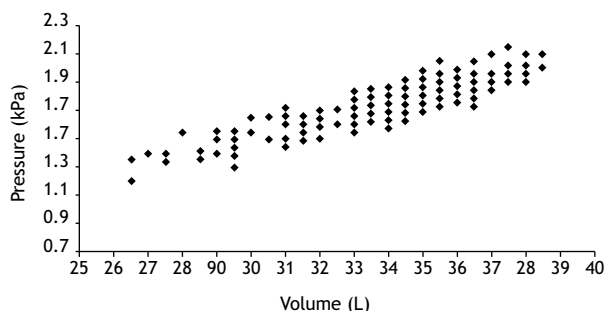


Figure. Graphic of insufflation test for one sample.

prioritized. Health oversight is not just a part of SUS responsibilities, but has priority due to its essentially preventive nature. The spirit of the corresponding legislation allows us to perceive and analyze ANVISA as a space for government intervention – via its functions and tools – to work in the interest of public health and the environment, toward adapting the production system of goods and services to the social demands of individual and community health, as well as to the needs of the health care system.

Conclusion

On the basis of our results, we concluded that the minimum requirements set forth in RDC 62/2008 for natural rubber latex male condoms have been used as the basis for condom certification. The laboratories that perform the tests prescribed in the resolution have direct relationships with the manufacturers or their representatives interested in marketing the product. Nevertheless, from the perspective of health oversight, a single nonconforming unit of condoms has serious implications for public health. Therefore, the National System of Sanitary Surveillance cannot dispense with the Public Health Laboratory for analysis of the quality of condoms manufactured and commercialized in Brazil.

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