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QUALITY EVALUATION OF FOUR BRANDS OF MALE CONDOMS MARKETED IN ADDIS ABABA, ETHIOPIA

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ABSTRACT: Condom is usually made up of thin rubber (latex) designed or is made of polyurethane to cover the penis sheath at closed one end that is inserted intravaginally during sexual intercourse for contraceptive purpose or as a means of preventive sexually transmitted diseases. Condoms should be safe, effective, user-controlled, non-prescription, easy to use and relatively cheap. The quality of the four different brand of condoms available in the local market was evaluated using standards given by international standards organization (ISO), such as; Bursting volume and pressure (inflation), width, length, thickness, electrical hole test, package integrity, lubricant quantity were done for each brand of condoms. The result showed that all sample of condoms have fulfilled the standards requirement set by ISO 407 and that all four brands of condom which is marketed in Addis Ababa Ethiopia are of safe, effective for the use.

INTRODUCTION: Condom: Male condom is defined as a wrap of waterproof material designed to cover the penis and prevent exchange of body fluids during sexual intercourse [1, 2, 3, 4]. 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 [5]. At the closed end, the condom is rounded and usually has a reservoir tip designed to store semen.

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Male condoms serve a dual function by protecting against both pregnancy and sexually transmitted infections (STIs) [5, 6]. Condoms must be of good quality to prevent unwanted pregnancy and transmission of STDs, including human immuno-deficiency virus (HIV) [1, 7, 8]. If condoms are not of good quality, consumers will be reluctant to use them and will continue to be at risk of infection or pregnancy.

Condoms with leak or break during use, the risk to the user may approach the risk of using no condom at all. Therefore, poor quality condoms can damage not only the health of the users but also the reputation of the agency or national body supplying the condoms. This ultimately will affect all family planning and STD/HIV prevention programs [9, 10, 11].

The presence of poor quality condoms on the market has posed a serious challenge in the fight against HIV/AIDS. Quality, especially poor quality, affects popular perception of the value of condoms, which can in turn have a major impact on the success of prevention [7].

Therefore, poor quality condoms can damage not only the health of the users but also the reputation of the agency or national body supplying the condoms. This ultimately will affect all family planning and STD/HIV prevention programs. Condoms are classified as Class II Medical Devices. According to ISO/TC157 developed standards, condoms are required to fit the penis properly, free from holes, have adequate physical strength so as not to break during use, correctly packaged for protection during storage, and correctly labelled [12].

Condom is widely used over the world, in Ethiopia it has been increase by five folds the last 10 years, [13, 14, 15] so it is unquestionable to ensure the safety, efficacy and quality of condom that are available in the market. The quality of four brands of condoms which is available in the local market was evaluated using non compendia methods set by ISO. The method includes; air bursting volume, leakage test, total lubricant quantity, length, width, package integrity.

EXPERIMENTAL:

Apparatus and Equipments: Enersol electric hole tester (Australia, Equipment ID=PHY-EHT-002), accurate inflation tester (Valndor, Sweden, Equipment ID, PHY-AIT-001-O06), micro balance (Metter Toledo, Switzerland, Equipment ID, PHY-BAL-005), condom thickness tester (Valendor, Equipment ID, PHY-CTT-001), condom length and diameter tester (Equipment ID, PHY-CLDT-001) graduated in 0.5 mm, oven (Equipment ID, PHY-OV-004), enersole package integrity tester (Equipment ID, PHY-PIT-001), glass wares of different size were used throughout the experimental work. Subsequent statistical treatments were done by transferring the date using Excel 2013, Origin 8.5.

Chemicals and Solvents: Isopropyl (2-propanol) made in UK), sodium chloride, made in Switzerland) and distilled water were used throughout the research work. Male condoms of four brands were collected from various drug retail outlets in Addis Ababa using random sampling technique. Details of the condoms evaluated in the study are given in **Table 1**.

TABLE 1: DETAILS OF DIFFERENT BRANDS OF CONDOMS COLLECTED FROM DIFFERENT RETAIL OUTLETS FOUND IN ETHIOPIA

S. no.	Description of condom	Batch no.	Mfg. Date	Exp. Date	Manufacturer
1	No Logo pack of 4 (Aid condom)	1A099	01/2011	12/2015	Unidus Corporation Seoil. (Korea)
2	Protector plus pack of 4 (Aid condom)	DBAID2380	02/2011	01/2016	Thai Nipp. Rub. Ind. (Thailand)
3	"Ribbed" sensation pack of 3 (marketed condom)	NWMD03-100613	06/2010	05/2015	Thailand
4	"love" sensation pack of 3 (marketed condom)	C13120611	06/2012	05/2017	Thailand

Methods: The quality of condoms was assed according to non- compendia standards' set by ISO 4074:2002. The quality of the samples was examined in seven parameters which includes; air bursting volume, leakage test, total lubricant quantity, length, width, package integrity and all the samples of condom were analyzed within their shelf life at the time of investigation.

Determination of Bursting Volume and Pressure of Condom: A specified length of condom is inflated with air, and the volume and pressure required to burst the condom are recorded. The bursting pressure shall be not less than 1 kpa and the bursting volume should be from 0.4 to 0.5 dm^3. Bursting volume and pressure was carried out under controlled temperature of (25 ± 5) ºC. The condom inside the package was removed, torn and unrolled to ensure that it was not stretched in any direction. For the test, 200 condoms in each brands were hanged on inflation apparatus and the bursting volume and pressure were measured.

Determination of total Lubricant Contain of Condoms: It is the process determination of mass loss of lubricant quantity which is removed by

washing with a solvent to the package and condom. Silicone fluid is the most commonly used lubricant for condoms it's because of inert and has minimal effect on the properties of the latex film. The quantity used has been selected to provide as high a level of lubrication as practical without creating package sealing problems in the factory. The solvent should be isopropyl, and lubricant quantity should not less than 250 mg and greater than 750 mg, if lubricant quantity is less than 250 mg the friction will be high which in turn results condom breakage and if lubricant quantity is greater than 750 mg its deleterious effect will be high that results low quality of condom.

To determination of total lubricant for condoms, thirteen condoms from each brand were weighed individually with their container to the nearest 1 mg and the results were recorded. Each condom was slot carefully around three edges and the condoms were removed undamaged from their container. The condoms had been cut up one side using scissors before unrolling them, and then the condoms were unrolled and wiped their lubricant and immersed in 400 ml propan-2-ol in a baker. Individual condom was washed for 2-5 min with agitation. The condoms were dried in oven for 5 min at 55 ºC and then each dried condoms were weighed.

Determination of Condom Length: The condoms were moved away from the area where the package was to be torn. The condom was unrolled and stretched slightly about 20 mm to smooth out the wrinkles caused by the condom having been rolled up. Lubricants were removed and powders were added to avoid sticking. 13 condoms were putted over the mandrel and they were hanging freely and measured to the nearest millimeter.

Determination of Condom Width: Condom width is defined as the width when the condom is laid flat; it is half the circumference. The relative circumferences of the condom and penis determine how well the condom fits. Excessively large or small condoms relative to penis size appear to increase the risk of failure. It appears from the limited information available that three widths of condoms will meet the needs of most of the population. Condoms of a width of 49 mm are readily available from many manufacturers, and this is therefore the preferred size for a narrower condom. The standard width for condoms is usually 52 to 53 mm (WHO/ UNFPA specify 53 mm ± 2 mm). There is no recognized size for larger condoms. Some manufacturers produce condoms of 56 mm width or more. Thirteen condoms were removed from the package, unrolled and laid flat over the edge of the ruler, perpendicular to the condoms axis. The right amount of talc powder were added to avoid sticking due to lubricant and measured.

Determination of Condom Thickens: The thickness range has been chosen to avoid both very thin and very thick condoms. The very thin products are likely to fail inflation requirements, while the very thick ones appear to offer no added efficacy and are likely to be less acceptable to users. The normal thickness range for condoms is between 0.060 and 0.080 mm. Condoms thinner than 0.060 mm are normally classified as thin, and those thicker than 0.080 mm are normally classified as thick. The method of determining thickness follows ISO and involves weighing a known area of the condom, then dividing by the density. Alternatively, the thickness may be determined using a micrometre with a foot diameter of (5 ± 2) mm and a foot pressure of (22 ± 4) kPa. Thirteen condoms were cut through their length using scissor, after it has been removed from its package. Then washed by isopropyl and it was dried for one day and the thickness were measured.

Determination of Condom Holes: This is the process by which checking holes for condoms, several studies have investigated the viral barrier properties of condoms that pass the tests for freedom from holes. These studies have demonstrated that intact condoms are, for all practical purposes, an effective barrier to the smallest viruses it has two alternative methods; the water leak test and the electrical test method. Water leak test is filling of the condom with a specified volume of water and examining for visible water leakage the condom through the wall of suspended condom. In the absence of any leakage the condom is then rolled on colored absorbent paper which is subsequently examined for signs of leakage of water from the condom. Electrical testing is the process by which the condoms are initially screened electrically to detect holes.

A condom which has no holes acts as insulator and allows no current to flow in an electrical circuit. Condoms were removed from their package and unrolled each condom by ensuring that it was not stretched in any direction excessively. The condoms examined visually to identify tears, holes, any visual defects (broken). The open end of the each condom was fitted onto the mount so that the condom was suspended open end upwards. The condom was filled about (300 ± 10) ml of electrolyte and a temperature between 10 and 40 ºC has been done for visible electrolyte leakage. The filled condom was submerged 25 mm from open end in to a container containing electrolyte for measuring voltage. A 10 v stabilized continuous voltage source in series with 10 kΩ high precision electrical resistance between the electrode in the container and the electrode inside the condom. Each condom was measured that the voltage greater than 50 mV at the resistor after (10 ± 2) sec.

Determination of Condom Package Seal Integrity: The purpose of the package is to protect the condom from mechanical damage, oxygen, ozone and light and to prevent lubricant from leaking. Exposure to oxygen, ozone and ultraviolet and visible light increases the risk of degradation of the condom. The test adopted is identical to that in ISO. It involves putting the packs under water in a transparent container and then drawing a vacuum on the container. The packs are observed for signs of rising bubbles while under vacuum. The vacuum is then removed and the packs are opened for evidence of ingress of any water. The presence of rising bubbles while under vacuum or the ingress of water into the pack after removing the vacuum indicates a leaking pack.

Thirty two condoms from the tested brands, with their package were submerged in to container which contained water and with the vacuum chambered. A dye added to the water, in order to detect leakage of water easily. The chamber evacuated to an absolute pressure of (20 ± 5) Kpa. The vacuum held for 1 min, the vacuum released and the packages of the condoms were checked for water inside or absorbing.

RESULTS AND DISCUSSION: In this study, four brands of male condoms were collected from retail outlet and tested according to ISO standards regarding bursting volume and pressure, lubricant, length, thickness, length, width, hole and package seal integrity as quality parameters.

Determination of Bursting Volume and Pressure of Condom: The condom is inflated with air until it bursts and the test challenges a large part of the surface area of the condom, and flaws in the latex film will reduce the burst volume and pressure of the condom.

TABLE 2: BURSTING PRESSURE OF FOUR DIFFERENT BRANDS OF CONDOMS AND THE PERCENT OF CONDOMS WITHIN THE BURSTING PRESSURE RANGE

Busting pressure (Kpa)	Percentages of condoms tested (%)			
	No logo	Protector plus	Ribbed sensation	Love sensation
<1.4	1	1	0	0
1.4-1.5	1	0	1	0
1.5-1.6	1	1	0	1
1.6-1.7	1	2	1	5
1.7-1.8	9	6	0	8
1.8-1.9	8	10	1	7
1.9-2.0	18	16	3	14
2.0-2.1	23	13	0	19
2.1-2.2	23	17	6	21
2.2-2.3	13	17	14	14
2.3-2.4	0	8	30	7
2.4-2.5	2	5	34	3
2.5-2.6	0	2	10	1
2.6-2.7	0	2	0	0
2.7-2.8	0	0	0	0
2.8-2.9	0	0	0	0
2.9-3.0	0	0	0	0
3.0-3.1	0	0	0	0
3.1-3.2	0	0	0	0

As shown in **Table 2** and **Fig. 1**, bursting pressure for were measured and 46% of no logo brand had the bursting pressure 2.0-2.2 Kpa, 34% of protector plus 2.1-2.3 Kpa, 64% of ribbed sensation 2.3-2.5 Kpa and 40% of love sensation 2.0-2.2 Kpa.

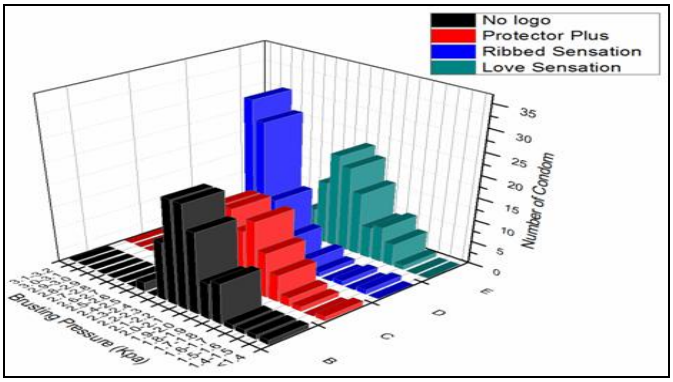

FIG. 1: BURSTING PRESSURE OF FOUR BRANDS AND THE PERCENT OF CONDOMS WITHIN THE BURSTING PRESSURE RANGE HISTOGRAM

Condoms with highest bursting pressure have better quality than less bursting pressure, with the highest pressure means that it protects high tension during sexual intercourse. From the four brands, ribbed sensation has got the highest bursting pressure, though all brands of condom within the required specification. The bursting pressure of all four brands of condoms differs in the mean and standard deviation value were calculated and given in **Table 3**. Ribbed Sensation brand, were showed the highest mean bursting pressure and the standard deviation is lower than the other. Even through, all brands were in the quality limit, no logo brands had showed low mean bursting pressure than the other three.

Bursting volume of the four brands was tested and 44% no logo 32-36L, 53% protector plus 28-32L, 52% ribbed sensation 32-36L and 47% love sensation 32-36L **Table 4** and **Fig. 2**. Therefore, it can be concluded that "Protector plus" condom has got the highest bursting volume capacity than the others. The bursting volumes for all brands were in the specification limit.

TABLE 3: DESCRIPTIVE STATISTICS OF BURSTING PRESSURE OF THE FOUR BRANDS OF CONDOMS

Different brands of condom	Bursting pressure in Kpa (N= 100)			
	Mean	Std. deviation	Minimum	Maximum
No logo	2.03	0.19	1.16	2.50
Protector plus	2.10	0.24	1.37	2.64
Ribbed sensation	2.34	0.18	1.45	2.58
love sensation	2.05	0.21	1.53	2.50

TABLE 4: BURST VOLUME OF FOUR BRANDS OF CONDOMS AND THE PERCENT OF CONDOMS WITHIN THE BURSTING VOLUME RANGE

Bursting volume (L)	Percent of condoms tested (%)			
	No logo	Protector plus	Ribbed sensation	Love Sensation
<18	0	1	0	0
18-20	1	0	0	0
20-22	0	1	1	0
22-24	1	4	1	1
24-26	4	3	1	1
26-28	6	20	1	1
28-30	13	21	6	7
30-32	18	32	11	20
32-34	25	13	25	24
34-36	19	3	27	23
36-38	9	2	20	21
38-40	4	0	7	2
40-42	0	0	0	0
42-44	0	0	0	0

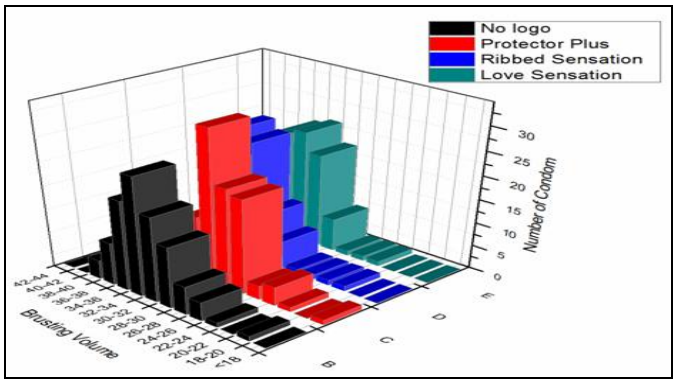

FIG. 2: BURSTING VOLUME OF FOUR BRANDS OF CONDOMS AND THE PERCENT OF CONDOMS WITHIN THE BURSTING VOLUME RANGE

The descriptive statistics for bursting volume were calculated and given in **Table 5**, and bursting volume of "No logo" were the highest standard deviation compared to the rest but Love Sensation was less standard deviation. Therefore, it can be concluded that "Love Sensation" have better quality condom compared to others in its uniformity of distribution but still all four brands of condom fulfil the quality parameters.

Determination of Total Lubricant Contain of Condoms: Lubricant quantity were measured and given in **Table 6**. Protector plus had the highest lubricant quantity in its individual container compared to others. All four brands had successfully passed the quality parameter for lubricate contestant set by ISO.

TABLE 5: DESCRIPTIVE STATISTICS OF BURSTING VOLUME OF THE FOUR BRANDS OF CONDOMS

Different brands of condom	Bursting volume in L (N= 100)			
	Mean	Std. deviation	Minimum	Maximum
No logo	32.1	3.7	18.0	40.0
Protector plus	31.5	3.2	19.7	38.6
Ribbed Sensation	34.0	3.2	20.9	39.6
Love Sensation	33.6	2.9	23.0	39.4

TABLE 6: TOTAL LUBRICANT QUANTITY OF THE FOUR BRANDS OF CONDOMS

Different brands of condom	Total lubricant quantity gram (N= 13)		
	Minimum	Maximum	Mean
No logo	0.4061	0.5854	0.47827
Protector plus	0.4467	0.5834	0.52562
Ribbed sensation	0.4197	0.5756	0.49582
Love sensation	0.4288	0.6856	0.49544

Determination of Condom Length: The length of condom were measured and the mean value also calculated and given in **Table 7**. Protector plus have got the highest length then other three, through all brands were in specified limit.

TABLE 7: DESCRIPTIVE STATISTICS OF LENGTH OF THE FOUR BRANDS OF CONDOMS

Different brands of condom	Length in mm (N= 13)		
	Minimum	Maximum	Mean
No logo	190	191	190
Protector plus	190	192	191
Ribbed sensation	190	192	190
Love sensation	190	191	190

Determination of Condom Width: The width of four brands of condoms were measured and compared against ISO quality standard limit. As shown in **Table 8**, all four brand of condom shown a results between 52 to 53 mm which is the requirement of ISO standards. Based on the result, all brands of condom complies with the requirements specification for condom width.

TABLE 8: DESCRIPTIVE STATISTICS OF THICKNESS OF THE FOUR BRANDS OF CONDOMS

Different brands of condom	Width in mm (N= 13)		
	Minimum	Maximum	Mean
No logo	52	52.5	52.25
Protector plus	52.5	53	52.75
Ribbed sensation	52	52.5	52.25
love sensation	52	53	52.5

Determination of Condom Thickens: As shown **Table 9**, the descriptive statistics of thickness of the four brands; "Ribbed sensation" and "Love sensation" has got the highest mean. Therefore, it can be concluded that "No logo" has better thickness. According to the relative thickness of the condom should not be very thin and very thick. But doesn't mean the other three condoms thick or thin. Very thin products are likely to fail inflation (bursting) requirement, while the very thick ones appear to offer no added efficacy. In addition to this, sensation ribbed condoms had ribbed on its surface, this will increase stimulation during sexual intercourse.

TABLE 9: DESCRIPTIVE STATISTICS OF THICKNESS OF THE FOUR BRANDS OF CONDOMS

Different brands of condom	Thickness in mm (N= 13)		
	Minimum	Maximum	Mean
No logo	0.057	0.070	0.063
Protector plus	0.056	0.069	0.062
Ribbed sensation	0.055	0.070	0.064
Love sensation	0.058	0.068	0.064

Determination of Condom Holes: Freedom from holes test was done using electrical test which is based on the principle that a condom without a hole will act as an insulator and allows no current to flow in an electrical circuit, while a condom with a hole will allow a current to pass. Based on our result from the test all four brands of condoms had pass the condom holes tests.

Determination of Condom Package Seal Integrity: For a package seal integrity test individual condom containers were submerged in a vacuum chamber containing water. The chamber was then evacuated at an absolute pressure of (20 ± 5) Kpa. As the vacuum increased the condom containers were observed for leakage in the form of a steady progression of bubbles. The vacuum was then released and condom containers were then observed for the presence of water inside. No air bubbles and no fluid inside means compliance with the standards. Package seal test also done based on the methods which explained above and all of the four brands of condoms has passed the test.

CONCLUSION: The four brands of condoms were according to ISO 4074:2002 specification with regard to bursting volume and pressure, lubricant quantity, length, width, thickness, electrical whole test, package integrity, ensured that

we can conclude that all four brands of condom which is marketed in Addis Ababa Ethiopia are passed the minimal quality specification which is set by ISO. Therefore the condom which is marketed in Addis Ababa is safe to prevent to unwanted pregnancy and sexually transmitted disease.

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