Evaluation of acceptability of the use of internal and external condoms in couples: a cross-over study

Avaliação da aceitabilidade do uso de preservativos internos e externos em casais: um estudo cross-over

Evaluación de la aceptabilidad del uso de condones internos y externos en parejas: un estudio cruzado

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Abstract

Objective: To evaluate the acceptability (comfort, ease of use, lubrication, and pleasure) of internal and external condom use in stable couples. Metodology: This randomized cross-over trial included 54 couples (108 adult individuals). Participants were asked to evaluate acceptability measures of both types of condoms using the Visual Analogue Scale. We developed a three-level hierarchical model [level 1= three repeated measures (wave, type of condom); level 2= individual (gender, age); level 3= couple (sequence of presentation of female versus external condom)]. Results: The "ease of use" dimension represented the biggest difference between the types of condoms for men (Hedges 'g = 0.96; p <0.0001) and women

(Hedges' g = 1.62; p <0.0001). Regardless of gender, external condoms performed better (1.61; 95% HPD = 1.41 – 1.81). Men gave lower scores in general (-0.62; 95% HPD = -1.16 − -0.10). Conclusion: The external condom scored better than the internal condom for women and their male partners. The scores tended to improve with the repetitive use of the condom. There is no evidence of the influence of the age of the individuals or the randomly selected sequence of use of condoms with regards to the mean score of the four dimensions.

Keywords: Condoms; Sexual health; Functional acceptability; Sexual behavior; Cross-over studies.

Resumo

Objetivo: Avaliar a aceitabilidade (conforto, facilidade de uso, lubrificação e prazer) do uso dos preservativos interno e externo em casais estáveis. Metodologia: Este estudo cross-over randomizado incluiu 54 casais (108 adultos). Os participantes foram convidados a avaliar as medidas de aceitabilidade de ambos os tipos de preservativos usando a Escala Visual Analógica. Desenvolvemos um modelo hierárquico de três níveis [nível 1 = três medidas repetidas (wave, tipo de preservativo); nível 2 = individual (sexo, idade); nível 3 = casal (sequência de apresentação do preservativo interno versus externo)]. Resultados: A dimensão "facilidade de uso" representou a maior diferença entre os tipos de preservativos para homens (Hedges 'g = 0,96; p <0,0001) e mulheres (Hedges' g = 1,62; p <0,0001). Independentemente do sexo, os preservativos masculinos tiveram melhor desempenho (1,61; 95% HPD = 1,41 – 1,81). Os homens deram pontuações mais baixas em geral (-0,62; 95% HPD = -1,16 – -0,10). Conclusão: O preservativo externo teve uma pontuação melhor do que o interno para as mulheres e seus parceiros masculinos. A pontuação tendeu a melhorar com o uso repetitivo do preservativo. Não há evidências da influência da idade dos indivíduos ou da sequência aleatória de uso do preservativo no que diz respeito ao escore médio das quatro dimensões.

Palavras-chave: Preservativos; Saúde sexual; Aceitabilidade funcional; Comportamento sexual; Estudos cross-over.

Resumen

Objetivo: evaluar la aceptabilidad (comodidad, facilidad de uso, lubricación y placer) del uso de condones interno y externo en parejas estables. Metodología: este ensayo cruzado aleatorio incluyó a 54 parejas (108 individuos adultos). Se pidió a los participantes que evaluaran las medidas de aceptabilidad de ambos tipos de condones utilizando la Escala Visual Analógica.

Desarrollamos un modelo jerárquico de tres niveles [nivel 1 = tres medidas repetidas (wave, tipo de condón); nivel 2 = individuo (género, edad); nivel 3 = pareja (secuencia de presentación del condón interno versus externo)]. Resultados: la dimensión "facilidad de uso" representó la mayor diferencia entre los tipos de condones para hombres (g de Hedges = 0,96; p <0,0001) y mujeres (g de Hedges = 1,62; p <0,0001). Independientemente del género, los condones externos se desempeñaron mejor (1,61; 95% HPD = 1,41 – 1,81). Los hombres dieron puntuaciones más bajas en general (-0,62; 95% HPD = -1,16 − -0,10). Conclusión: el condón externo obtuvo mejores resultados que el condón interno para las mujeres y sus parejas masculinas. Las puntuaciones tendieron a mejorar con el uso repetitivo del condón. No hay evidencia de la influencia de la edad de los individuos o de la secuencia aleatoria de uso del condón con respecto al puntaje promedio de las cuatro dimensiones.

Palabras clave: Condones; Salud sexual; Aceptabilidad funcional; Comportamiento sexual; Estudios cruzados.

1. Introduction

Traditionally, researchers have focused efforts on increasing condom use for HIV/AIDS prevention. Proper and consistent condom use remains the most effective way to reduce sexually transmitted infections (STI), including HIV/AIDS and unplanned pregnancies. However, this method depends on the acceptability of the device, and the couple's willingness and acceptability to use it in all sexual relations (Sanders, Hill, Crosby, & Janssen, 2014; Jones, Tiwari, Salazar, Crosby, 2018; Shen et al., 2019).

In spite of the importance of condom acceptability and performance for consistent use, currently existing scales have had mostly behavioral approaches, such as Condom Uses Self Efficacy Scale (CUSES), by Brafford and Beck (1991), validated in Ghana (Asante & Doku, 2010); Condom Self Scale (CSE), the same instrument validated in Brazil (Sousa et al., 2017); Attitude Toward Condoms Scale (ATC), by Brown (1984); Condom Attitude Scale (CAS) by Sacco, Levine, Reed, and Thompson (1991); Sexual Attitude Scale (SAS) by Alferes (1999); Multi-factor Attitude Toward Condoms (MFACS), by Hollub, Reece, Herbenick, Hensel, and Middlestadt (2011); Sexual Sensation Suking Scale (SSSS) evaluated by Kalichman and Rompa (1995), and validated in Spain (Iglesias, Moyano, Castro, Granados, & Sierra, 2018).

In the last decades, as far we could investigate in international databases, there is a dearth of studies with a robust methodology that clarifies the factors that influence the use or

no-use of condom. Moreover, we did not find any cross-over study on this theme that compared the external condom (male condom) with the internal condom (female condom), in the perception of both men and women. Studies primarily address dimensions related to sexual knowledge, attitudes, or behavior (Fonner, Kenned, O'Reilly, & Sweat, 2014; Beksinska et al., 2015; Wang et al., 2015; Ting, Wong, & Tnay, 2018; Ting et al., 2019). When the approach was focused on condom acceptability, they analyzed only one type (Siegler et al., 2019; Chen et al., 2019).

Factors that limit the acceptability of condoms include slippage, poor esthetics, lack of lubrication, pain on use and difficulty in insertion (Reece, Herbenick, & Dodge, 2009; Wanyenze et al., 2011; Peixoto, Botelho, Tomada, & Tomada, 2016; Bowling et al., 2018). In addition, there is a growing consensus that issues related to pleasure and condoms deserve to be considered. Common perceptions that condoms interfere with pleasure and sexual function can lead to abandoning condoms to preserve high levels of sexual satisfaction (Bojko et al., 2010; Choudhry, Agardh, Stafström, & Östergren, 2015; Siegle et al., 2019).

The objectives of this research are to evaluate the acceptability of internal and external condom use in steady couples; compare the acceptability of the external condom with the internal condom and assess differences in perception according to sex. We quantitatively evaluated both devices in four dimensions (comfort, ease of use, lubrication, and pleasure) as well as by making predictions of the average mean score of such dimensions.

2. Methods

2.1. Study Design and Participants

This is a randomized cross-over clinical study to compare the acceptability of external condom (EC) and internal condom (IC) in female and male perception. In crossover studies, each subject function as its own control, and the comparison of the different interventions is the comparison of the intrasubject variation. Since each subject is his own control, the prognostic factors are balanced between the groups (Friedman et al., 2015).

Participants were recruited from a between February and April 2019 within the Comprehensive Care Center for Women's Health (CCCWH). The CCCWH gives free assistance, clinical exams, STI counseling, and distribution of condoms to women. The students and collaborators, as well as the neighboring community and adjacent to the University, can

use the service. After agreeing to participate in the survey, the women invited their partner and confirmed the couple's participation. The project was submitted and approved by the Ethics and Research Committee of Tiradentes University (report No. 2,824,264 and CAAE 92638418.3.0000.5371). All participants signed an informed consent form.

We selected women aged 18 to 45 years, with active sexual life and steady partner. Women who reported previous allergic reactions to nitrile rubber and / or latex, pregnant, menopausal, with some vulvovaginal condition or individuals under some medical treatment for severe illness were excluded.

The sample size (50 couples) was estimated according to the following parameters: minimum detectable difference (between-group and within-group) in the scores of the analogic scale = 1.5 points; two randomly selected stages (AB and BA); two-tailed p value <0.05; power = 80%; standard deviation = 3; adjustment for clustering effect by couples; intraclass correlation coefficient (rho) = 0.7. Additionally, we performed simulations of rho levels (from 0.2 to 0.8), and standard deviation (from 1 to 5), which indicate that, for the estimated sample size, in extreme conditions, it is still possible to identify a lower minimum difference to 2 points on the visual analogic scale. In order to avoid loss of power due to eventual drop-outs, we increased the initial sample by 20% (60 couples, 120 individuals).

2.2. Procedures

After agreeing to participate in the survey, the women were interviewed individually and informed about the next steps that would involve the presence of the sexual partner. We took care to provide information on correct condom use for each couple and use acrylic and rubber models of the female pelvis and penis to demonstrate proper use of each type of condom.

The sequence of use of external as well as internal condoms was randomized (EC→IC or IC→EC). The individuals did not undertake a wash-out period because we assume there is no ground for systemic interactions, local or residual effects of condom use. The interval of use of each condom was at the discretion of the couple since three condoms were used within one month in each sequence. There was an average interval of 10 days between the use of each condom per couple. We strongly recommended not to apply any additional lubricant.

Under this scheme, for the first phase, three units of female or external condoms were delivered, depending on the order of randomization for the couple. The individuals were given six visual analog scales as well as for instructions on how to be filled after the use of each

condom. After the use of three units (external condom or internal condom), depending on the randomized sequence, the individuals returned to the CCCCH, where they were interviewed and questioned about possible doubts or difficulties during the process. Each couple was supposed to give back the visual analog scales in order to start with the second phase. Then, they were given another three condoms units, this time of a different type. After one month, they returned and presented the three visual analog scales concerning phase 2.

The condoms used in the study are distributed free of charge by the Ministry of Health through the Department of Chronic Conditions and Sexually Transmitted Infections. The Sergipe State Health Department provided the necessary condoms for the research, and the expiration date and state of preservation of the product were observed.

The internal condom, an FC2 (second generation female condom), is one-size-fits-all (15cm x 8cm in diameter), with two flexible rings at the ends, where one is inserted into the vagina and the other covers the labia. It is composed of nitrile rubber, pre-lubricated and is manufactured by The Female Health Company in Malaysia. The external condom has 16cm of length and a diameter of 5.2 cm; it is made of natural rubber, latex, pre-lubricated and manufactured by HLL Lifecare Limited in India.

2.3. Measures

Six items assessed socioeconomic aspects, including age, gender (female and male), education level: (illiterate, incomplete o complete elementary education, secondary education, higher education, specialization, and master's degree), occupation, self-declared skin color (white, brown and black) and social status through the score entitled Brazilian Economic Classification Criteria items in the home for purposes of economic classification, questions about type of water supply and paving of the streets in which they reside, and questions concerning the schooling of the interviewee). Finally, there is a sum of points of the items contained in the Brazilian Economic Classification Criteria (Brazilian Association of Companies and Research, 2018) that allows everyone to be classified into 7 socioeconomic classes, namely A, B1, B2, C1, C2, D, and E. Each social class has an average family income value, these values were presented in dollars according to the Central Bank of Brazil Currency Quotation.

Patient's clinical and medication history was presented through the following items: consumption of alcohol, smoking, pre-existing diseases, and current treatments, except

contraceptive treatment. Anthropometric measurements were collected to calculate the Body Mass Index (BMI), whose formula is represented by Weight (kg)/Height(m)².

The visual analogue scale allowed the evaluation of the couples after the use of the condoms, ranging from zero to 10. Zero reflected the worst experience, and ten conveyed the best experience. Scores were given to each dimension (comfort, ease of use, lubrication, pleasure, and general perception of the use).

2.4. Statistical Analysis

Categorical variables were presented as absolute numbers and percentage, and comparisons were made under the Fisher's exact test. Continuous variables were presented as mean and standard deviation, discrete variables were presented as median and interquartile interval, and comparisons were made under the Mann-Whitney test. The Hedges g was estimated to convey effect size.

We elaborated a three-level hierarchical model (Figure 1): the repeated measures concerning condom acceptability (level 1); individuals (level 2); couples (level 3). We included predictors related to level 1 (wave, type of condom), level 2 (gender, age) as well as level 3 (sequence of presentation of internal versus external condom).

Figure 1. Three-level hierarchical model for condom use by research by couples.
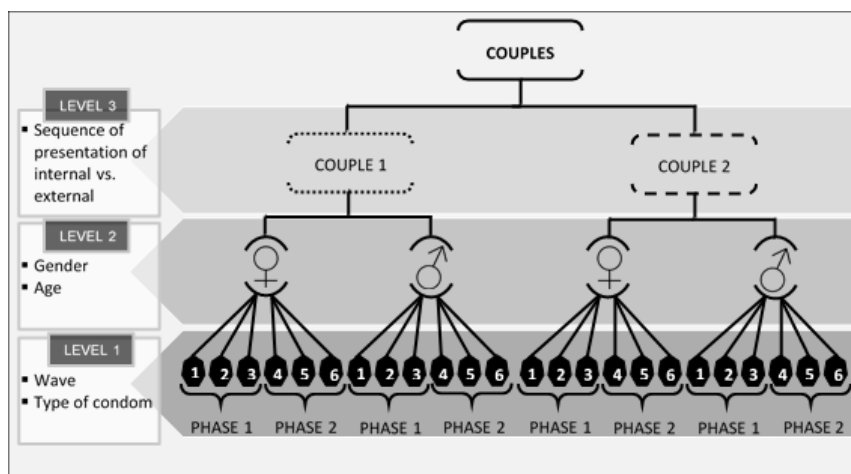
Source: Authors.

The point estimates were presented as mean and median coefficients, and the measures of dispersion were presented as highest density credible intervals (HDI) and Monte Carlo standard errors (MCSE). We initially adopted the following priors as well as hyper-priors concerning the mean (mu) and variance (sigma2) of the parameters, the residuals for each level

and the residual covariance between levels, respectively: normal, mu = 0, sigma2 = 100; normal, mu = 0, sigma2 = variance of residuals; inverse gamma, mu =0.01, sigma2 = 0.01. In order to avoid potential collinearity between couples and individuals, the analysis was performed under blocks concerning each level.

We applied 12,500 Markov Chain Monte Carlo (MCMC) iterations under adaptive Metropolis-Hastings algorithm and Gibbs sampling, with a burn-in phase of 2,500 iterations. In case of substantial autocorrelation for a given parameter, we applied the following strategies to reach a fixed pattern of distribution: increasing the burn-in phase; thinning of the MCMC sampling; estimating the variance of the parameter in a separate block.

We selected the most appropriate model according to the following criteria: a) highest acceptance rate and average efficiency; b) lowest autocorrelation; c) normal distribution of posteriors, verified in histograms, kernel density curves, and quantile-quantile plots; d) homogeneity of dispersion in trace plots; e) lowest value of the deviance information criteria (DIC); f) highest values of the effective sample size for each parameter; g) optimal convergence of multiple chains, indicated by the potential scale reduction factor (PSRF) close to 1 and its upper confidence limit < 1.2 for each parameter; h) parsimony, defined as the point where adding complexity to model would not produce further improvement, was checked by estimating Bayes factors.

Additionally, the most appropriate model shall provide the highest log of the maximum likelihood, calculated by using the Laplace-Metropolis approximation, and the highest probability of fit of the dependent variable within the given data. Interaction terms were only included in the model according to these criteria.

Rounds of sensitivity analysis were performed for different choices of prior distributions concerning the relationship between the regressand and the predictors, and the addition of random slopes for the coefficients. Also, within a frequentist frame, we calculated the estimates for a multilevel model under maximum likelihood and unstructured variance-covariance matrix. All the calculations were performed in Stata (College Station, Texas) version 15.1.

3. Results

During the 3-month recruitment period, 120 eligible individuals agreed to participate at the beginning of the study. Twelve participants (10%) dropped out of the study; that is, 54 couples participated in the sample. When comparing the sample versus dropout data, there was

no difference related to age (27 ± 7.5 vs. 26 ± 7.6, p = 0.5866) or body mass index (25 ± 4.5 vs. 23 ± 3.8; p = 0.2844).

Most of the participants were brown (66.67%); all of them identified themselves as heterosexuals and had an average of 6 years of relationship with their respective partner. All participants had used a condom at least once before the invitation to the survey. However, 72 participants (66,67%) reported not to use condoms with the intention of preventing STI (Table 1).

Table 1. Descriptive characteristics of participant sample.

	Value
Age, mean ± SD	27.3 ± 7.5
Color, n (%)	
White	22 (20.4)
Black	14 (12.9)
Brown	72 (66.7)
Social status - Average Household Income †, n (%)	
A - US\$ 6,020.97	8 (7.4)
B1 - US\$ 2,678.80	14 (13.0)
B2 - US\$ 1,383.23	48 (44.4)
C1 - US\$ 764.88	30 (27.8)
C2 - US\$ 436.24	8 (7.4)
Occasional drinker, n (%)	
No	75 (69.4)
Yes	33 (30.6)
Smoking, n (%)	
No	105 (97.2)
Yes	3 (2.8)
Body mass index, mean ± SD	25.3 ± 4.5
Diabetes, n (%)	
No	106 (98.1)
Yes	2 (1.9)
Dyslipidemia, n (%)	
No	106 (98.1)
Yes	2 (1.9)
Hypertension, n (%)	
No	107 (99.1)
Yes	1 (0.9)
In use of medication††	
No	102 (94.4)
Yes	6 (5.6)
Relationship time, mean ± SD	5.6 ± 4.9
Condom use for prevention STI, n (%)	
No	72 (66.7)
Sometimes	16 (14.8)
Yes	20 (18.5)
Sequence, n (%)	
Internal condom → External condom	52 (48.1)
External condom → Internal condom	56 (51.9)

Note. SD: Standard deviation; STI: Sexually Transmitted Infections. † Value of the dollar against the Real in the quotation of June 10, 2019. ††Except the use of contraceptive medicines. Source: Authors.

With regards to the addictive behavior of the participants, 2.78% were smokers, 30.56% occasional drinkers, and there was no report of frequent use of alcohol. The 108 subjects were mostly healthy; only one referred to hypertension, two diabetics, two dyslipidemia and six used some medication (Table 1).

The variables for the analogue scale were compared according to gender and type of

condom (Table 2). We used an average mean score for all four dimensions and the external condom was better evaluated for both men (Hedges 'g = 0.62; p <0.0001) and women (Hedges' g = 0.87; p <0.0001).

Table 2. Evaluation of the acceptability of condom use by gender and type of condom.

	Male										p value[*†]	Hedges g	Female										p value[*†]	Hedges g
	Internal condom					External condom							Internal condom					External condom						
	Mean	SD	Median	P25	P75	Mean	SD	Median	P25	P75			Mean	SD	Median	P25	P75	Mean	SD	Median	P25	P75		
Comfort											<0.0001	−0.5135											<0.0001	−0.7430
Phase 1	4.7	2.9	4.0	2.5	7.0	6.1	2.7	6.0	6.8	7.0			5.1	2.9	4.5	2.0	7.5	7.0	2.1	7.3	6.0	8.5		
Phase 2	4.8	3.0	4.0	3.0	8.0	6.3	2.4	4.0	4.5	4.0			5.3	2.7	5.0	3.0	8.0	7.1	2.4	8	6.0	9.0		
Phase 3	4.9	2.9	4	3.0	8.0	6.4	2.5	8.0	8.0	8.0			5.5	2.8	5.0	3.0	8.0	7.3	2.2	8	6.0	9.0		
Ease of use											<0.0001	−0.9569											<0.0001	−1.6161
Phase 1	4.0	2.9	3.7	1.0	6.0	6.7	2.3	7.0	7.0	8.0			3.7	2.9	3.0	1.0	6.0	8.3	1.9	9.0	8.0	10.0		
Phase 2	4.6	2.7	4.0	2.0	7.0	6.8	2.4	5.0	5.0	5.0			4.4	2.8	4.0	2.0	7.0	8.1	1.9	9.0	7.0	9.0		
Phase 3	4.6	2.6	4.3	3.0	6.0	7.1	2.4	9.0	9.0	9.0			4.7	2.7	4.0	3.0	7.0	8.2	2.0	9.0	7.0	9.5		
Lubrication											0.0010	−0.3788											0.4475	−0.0656
Phase 1	5.7	2.6	6.0	4.0	8.0	6.5	2.5	7.0	7.0	7.5			6.7	2.2	7.0	5.0	8.0	6.6	2.2	7.0	5.0	8.0		
Phase 2	5.8	2.6	6.0	3.2	8.0	6.8	2.4	4.0	5.0	5.0			6.6	2.2	7.0	5.0	8.0	6.7	2.2	7.0	5.0	8.0		
Phase 3	5.8	2.6	5.9	4.0	8.0	6.9	2.4	9.0	9.0	9.0			6.6	2.3	7.0	5.0	8.5	7.0	2.4	7.8	6.0	9.0		
Pleasure											0.0053	−0.3469											<0.0001	−0.4888
Phase 1	5.5	3.1	5.8	4.0	8.0	6.4	2.5	6.3	5.0	8.0			6.1	2.6	6.0	4.0	8.0	7.3	2.1	8.0	6.0	9.0		
Phase 2	5.6	2.9	5.5	4.0	8.0	6.6	7.0	7.0	4.0	9.0			6.0	2.7	6.0	4.0	8.0	7.1	2.4	7.8	6.0	9.0		
Phase 3	5.7	2.9	6.0	4.0	8.0	6.8	7.0	7.0	4.5	9.4			6.0	2.7	6.0	4.0	8.0	7.3	2.4	8.0	5.0	9.0		
Overall											<0.0001	−0.6208											<0.0001	−0.8670
	5.1	2.4	4.9	3.5	7.0	6.6	2.2	6.9	5.3	8.4			5.5	2.2	5.5	3.8	7.3	7.3	1.8	8.0	5.9	8.8		

Note. SD: Standard deviation. *Wilcoxon Test. †The size of the effect was calculated by the Hedges g.
Source: Authors.

The "ease of use" dimension showed the largest difference between condom types for both men (Hedges 'g = 0.96; p <0.0001) and women (Hedges' g = 1.62; p <0.0001), in which internal condom obtained a lower score compared to external condom (Table 2).

We elaborated a three-level hierarchical model – Level 1= 3 repeated measures; Level 2= individual; and Level 3= couple (Table 3). In order to tackle collinearity as well as autocorrelation, we included the waves for each measurement as a slope, and we selected an unstructured matrix of variance and covariance for the residuals. This was considered the most appropriate model since, when compared to several models, it provided the lowest BIC (Bayesian information criteria) and a p-value < 0.001 for the likelihood ratio test. We checked the residuals for each level, and they presented a normal distribution. As expected, the intraclass correlation was relevant for within-group (0.48; 95% IC = 0.34 – 0.63) estimations, and this strongly favors a multi-level approach.

Table 3. Model with estimating Bayes factors for the acceptability evaluation of condom use, adjusted for variables of level 1, level 2 and level 3.

	Mean	95% HPD CRI	
Gender (reference = female)			
Male	−0.62	−1.16 —	−0.10
Type of condom (reference = internal condom)			
External condom	1.61	1.41 —	1.81
Sequence (reference = internal condom → external condom)			
External condom → Internal condom	−0.22	−1.15 —	0.72
Wave (reference = 1)			
2	0.13	−0.12 —	0.37
3	0.28	0.38 —	0.53
Age (mean)	−0.01	−0.05 —	0.67

Note. Marginal likelihood (ML) is computed using Laplace-Metropolis approximation. The effective sample size for the variables as well as the parameters ranged from 72% to 100% of the Monte Carlo Markov chains. Stationarity was satisfactorily achieved, since the correlation time 1 to 4.51. HPD: Highest Posterior Density. CRI: Credible Intervals. Source: Authors.

Men gave lower scores in general (–0.62; 95% HPD = -1.16 — -0.10). The external condom had a better acceptability assessment for both genders (1.61; 95% HPD = 1.41 —1.81). The scores tended to improve with the repetitive use of the condom (Table 3). Figure 2 illustrates the identification of predictors of acceptability for condom use.

Figure 2. Predicted mean scores for the acceptability evaluation of condom use by gender, condom type, and sequence of measurements.
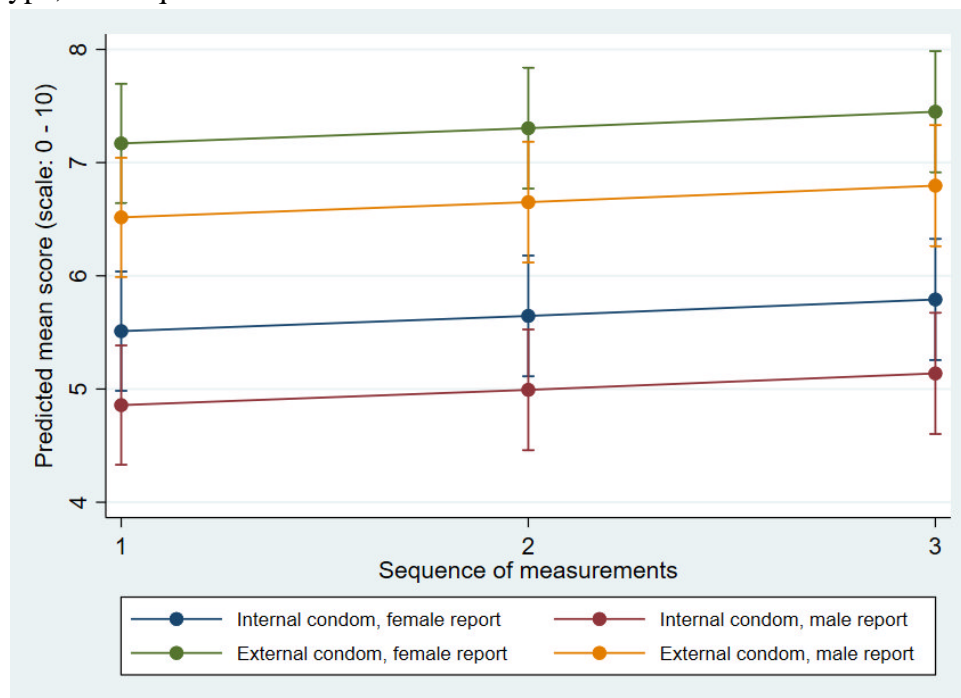
Source: Authors.

It is noticed that, men and women better evaluated both types of condoms after repeated use. In addition, the figure also illustrates that the male condom was better rated by both sexes and men had less general acceptance for both types of condoms (Figure 2). In continuity, Figure 3 illustrates the estimates for predicted mean acceptability scores of condoms use.

Figure 3. Bayesian point estimates and 95% credible intervals for predicted mean acceptability scores of condom use based on the three-level hierarchical model.
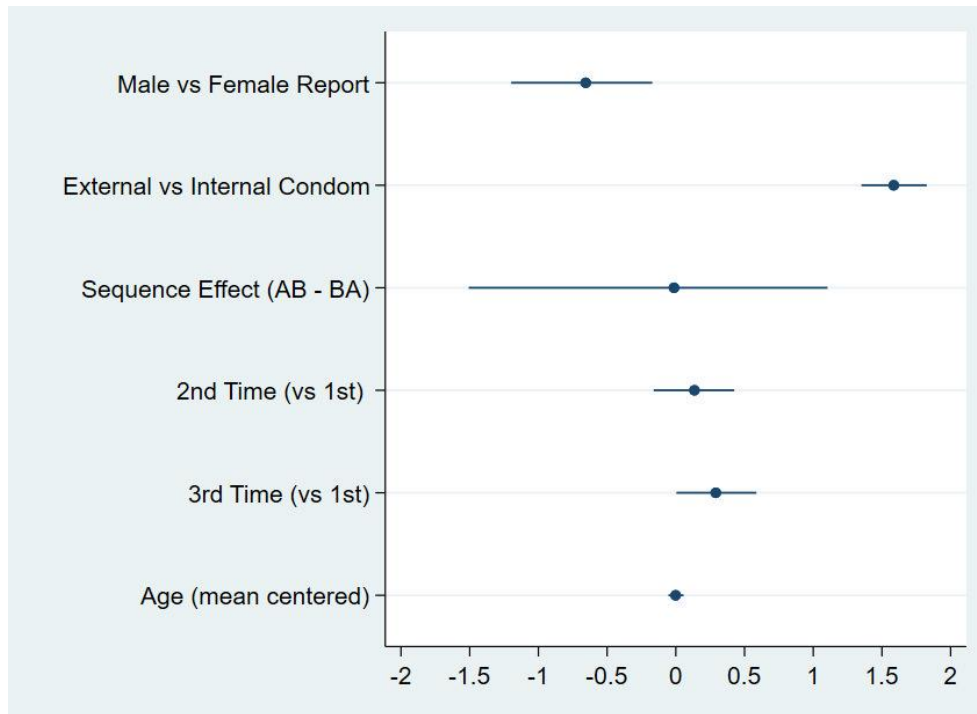
Source: Authors.

Based on the model, the probability of female's mean score at least 0.2 points above men is 95%. There is no evidence of influence of the age of the individuals or the randomly selected sequence of use of condoms with regards to the mean score of the four dimensions (Table 3 and Figure 3). As for the type of condom, the probability of the external condom reaching at least 1.4 points higher than the internals' is 98%.

4. Discussion

This cross-over study evaluated condoms acceptability by comparing male versus internal condoms. By using the Visual Analogue Scale as a framework for exploring female and external condom acceptability, we were able to identify factors that interfere with the

perception of adult women and men. This trial evaluated steady partners, allowing for a better understanding of a population that generally has less adherence to condom use.

The three-tiered hierarchical model elaborated in our study revealed that internal condoms had lower overall scores than the external condom. Besides, men rated lower scores than women for both types of condoms. Similar results have been found in previous research where women reported better acceptability results for condom use than men (Louw, Peltzer, & Chirinda, 2012; Closson et al., 2028) and the external condom obtained higher acceptability (Kulczycki, Kim, Duerr, Jamieson, & Macaluso, 2004; Chen et al., 2019).

A multicenter study conducted in the United States assessed the acceptability of the internal condom, and women referred dissatisfaction concerning a specific design or another sort of inconvenience, such as a potential decrease in pre-lubrication (Chen et al., 2019). A previous study mentioned due concern with the theme of the technique of insertion of the internal condom, as well as the appearance of the device. The authors reported that some individuals considered the internal condom too noisy, confusing, or unattractive (Kulczycki et al., 2004). Several internal-condom designs have been under evaluation to improve the acceptability of this device (Beksinska et al., 2012, 2013, 2015).

In our study, we also observed that the scores were lower during the first period of condom use compared to the second and third period of use, regardless of condom type. Subsequent use had a positive effect at each phase of the study, and the results suggest that creating a use condom habit may produce a positive impact on the acceptability of both types in the short term. Previous studies with condom-related intervention have shown positive results regarding subsequent timely use (Beksinska et al., 2015; Chen et al., 2019).

Additionally, there is a growing consensus that issues of pleasure in safe gender deserve to be considered (Siegler et al., 2019). However, other dimensions deserve similar attention and ease of use may be taken as a handicap related to the type of device. These specific concerns may encourage future studies for design improvements, particularly for the internal condom.

Among the limiting factors of this study, we can mention the fact that minority populations (such as Native-Americans) as well as low-income classes were underrepresented. Future studies could employ more focused recruitment activities for the population with lower socioeconomic status. Additionally, although users already have at least some prior condom experience, we did not collect information about the time since last use and the frequency of use, which would indicate the level of experience.

Among the potentialities, this randomized cross-over multilevel study incorporated an assemblage of dimensions concerning pleasure, comfort, lubrication, and ease of use. For this, we applied a systematic recruitment strategy that achieved favorable adherence (90%) when compared to other randomized trials with condom use interventions (Maksut & Eaton, 2015; Stone et al., 2018; Downs et al., 2018). Participants who dropout had reasons not related to the intervention, but due to the couple's lack of free-time and distance from the institution. Feedback from participants indicated strong acceptance and approval of the intervention. The increase in score results after continued use lead to reflect on the possibility of short-term interventions to encourage consistent condom use.

5. Conclusion

The three-level hierarchical model identified acceptability predictors for condom use. External condom scored better than the internal condom for both women and their male partners. Compared to men's ratings, both types of condoms scored better in the women's assessment. In general, the score given to condoms was also increased with the frequency of use.

Future studies are needed to confirm the influence of continued condom use on its acceptability. In addition, research with a quantitative and qualitative approach could study the reasons for men and women to evaluate condom use differently.

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