

Sex Transm Dis. Author manuscript; available in PMC 2011 June 1.

Published in final edited form as:

Sex Transm Dis. 2010 April; 37(4): 228–233. doi:10.1097/OLQ.0b013e3181bf9b2d.

Why Rectal Douches May Be Acceptable Rectal-Microbicide Delivery Vehicles for MSM

Alex Carballo-Diéguez, Ph.D.¹, José Bauermeister, Ph.D.², Ana Ventuneac, Ph.D.¹, Curtis Dolezal, Ph.D.¹, and Kenneth Mayer, M.D.³

¹HIV Center for Clinical and Behavioral Studies at New York State Psychiatric Institute and Columbia University, New York, USA ²Department of Health Behavior and Health Education, School of Public Health, University of Michigan, Ann Arbor, Michigan ³Fenway Institute, Fenway Community Health, Boston, Massachusetts, and Miriam Hospital/Brown University, Providence, Rhode Island

Abstract

Rationale—To explore age of onset of rectal douching among men who have sex with men (MSM) and reasons leading to and maintaining douching behavior; and to consider whether rectal douches containing microbicidal agents might be acceptable for men at HIV risk.

Methods—In Stage 1, we used qualitative methods to explore douching behavior in a sample of 20 MSM. Subsequently, we developed a structured questionnaire that was administered in Stage 2 to 105 MSM.

Results—More than half of participants who completed Stage 1 douched during the trial despite having been advised not to do so. Of the 105 HIV uninfected participants in Stage 2, 51% reported using rectal douches in the prior six months; 47% douched before and 25% after anal intercourse. Most participants reported douching frequently or always. On average, men reported douching about two hours prior to or one hour following intercourse. Average age of onset was late 20s. Most men who douched wanted to be clean or were encouraged to douche by their partners. Some men thought douching after sex could prevent STIs.

Conclusion—Rectal douching appears to be a popular behavior among men who have RAI. It is necessary to identify harmless douches. If HIV/STI preventive douches can be developed, rectal douching prior to or following sexual intercourse could become an important additional prevention tool. To reshape an existing behavior to which some men strongly adhere, like douching, by suggesting use of one type of douche over another may be more successful than trying to convince MSM to engage in behaviors they never practiced before or those they resist (e.g., condom use).

Keywords

receptive anal sex; "bottom," homosexual; douching; microbicide								
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All correspondence and reprint requests should be sent to Alex Carballo-Diéguez, Ph.D., Unit 15, New York State Psychiatric Institute, 1051 Riverside Drive, NY, New York 10032, USA, +1(212)543-5261 (telephone), +1(212)543-6003 (fax), ac72@columbia.edu.

Introduction

Men who have sex with men (MSM) use rectal douches when they have receptive anal intercourse (RAI), yet specific aspects of rectal douching (RD) practices are poorly understood. Given that RD is associated with HIV/STIs,1⁻7 studies of factors leading to onset and maintenance of RD are needed. Furthermore, considering that douches with soapsuds and tap water result in surface epithelium loss, which may facilitate HIV acquisition, but no epithelial damage is observed with the use of polyethylene glycol electrolyte solutions,8⁻9 it is important to know which products MSM use to douche prior to sexual intercourse. Better knowledge of RD is important for the field of rectal microbicides, products currently under development that could eliminate or decrease the chances of HIV infection when applied topically in the rectal compartment. In the case of vaginal microbicides, use of vaginal douches, dissectants, and cleansing with fingers, may affect the vaginal compartment in which the microbicide is expected to work.10⁻12 Similarly, RD may also affect the rectal compartment and may need to be accounted for during the development of rectal microbicides.

Few studies have focused on the behavioral aspects of RD associated with RAI. Hylton and colleagues 13 held focus groups with 16 men ages 19-61 and found that "enema use in preparation for sex was typical; the most commonly used enema was tap water; other enemas reported were over-the-counter products, soap and water combined, Epsom salts and glycerin." In a recent study 14 with a sample recruited in New York City, we explored RD practices among 105 men who engage in "barebacking," purposeful unprotected anal intercourse in risky circumstances.15 Participants reported that RD associated with RAI started, on average, at age 25, somewhat later than average age at first RAI reported in other studies.16 We found that 53% of HIV-negative and 96% of HIV-positive participants douched in preparation for sex, most of them frequently or always, mainly for hygienic purposes; 27% of HIV-negative and 44% of HIV-positive men douched after sex, partly believing douching protected from infections. These results highlight that the behavior is very popular among men at the highest HIV transmission risk. However, given this study's focus and sample, it left unanswered whether men with a different profile in other parts of the country may exhibit different douching behavior.

The present study, conducted with participants recruited in Boston, MA, seeks to contribute to the available scientific literature by using a mixed methods approach to study the circumstances that lead to the initiation and maintenance of RD associated with sex, the prevalence of RD, and the specific method for RD reported by a sample of HIV-negative men who engage in sexual risk behavior.

Materials and Methods

Data for this report come from a rectal microbicide acceptability trial17⁻18 conducted in Boston, MA, between June, 2004 and March, 2007. The trial consisted of two consecutive stages (a volume escalation stage and a formulation preference stage) during which we collected the data on RD. The Institutional Review Boards of participating institutions approved study design and procedures.

Eligibility Criteria and Procedures

The study was advertised with flyers and Internet postings. To qualify for the study, individuals had to be men, at least 18 years old, HIV uninfected, reporting unprotected RAI in the prior year (regardless of whether they called it barebacking) in circumstances that could result in their becoming infected with HIV, and have a male partner with whom they engaged in RAI at least once every two weeks. The same overall eligibility criteria was used

for Stages 1 and 2, with the exception that in Stage 1, we excluded candidates who reported regular (i.e., twice a week or more) RD --we considered that the rectal manipulation involved in douching and the use of different douching solutions could confound acceptability results. Furthermore, we advised participants to avoid douches during the trial, and we assumed that individuals with low frequency of douching or no douching would heed the advice. Nevertheless, at the time of the exit interview, many men disclosed having used douches (as will be explained below), which led us to remove the exclusionary criterion related to douches from Stage 2 of the study. Participants in each stage of the study were compensated up to \$230 if they completed all study procedures (see Carballo-Diéguez et al.17 and 18 for more details).

Stage 1 - Qualitative Measures

Participants in Stage 1 underwent a baseline, semi-structured qualitative interview that covered, among other topics, a description of recent anal intercourse experiences and rectal hygiene practices (including RD). These topics were discussed again at the end of Stage 1, using the same qualitative methods. The interviews were conducted by a male research assistant trained in in-depth interviewing who followed a pre-established interview guide. Interviews lasted about 30 minutes. Data from the qualitative interviews were subsequently used to develop a quantitative assessment to explore the prevalence and frequency of douching practices among MSM who would participate in Stage 2.

Stage 2 - Quantitative Measures

Participants in Stage 2 responded to a baseline Computer Assisted Self Interview (CASI) that included questions on demographic information, sexual behavior, and douching practices.

Data Analytic Strategy

Stage 1 qualitative interviews were audio recorded and transcribed. Based on content areas assessed and an initial transcript review, investigators identified categories and themes and developed a codebook. Using the software NVivo, transcripts were coded independently by two staff members who then compared the codes and discrepancies, and discussed them until reaching consensus. Core reports were synthesized following re-reading of textual data and discussion by the research team. Quotes that exemplified a topic were selected by the first author (ACD).

CASI data collected in Stage 2 were analyzed using SPSS to describe the prevalence of different douching practices in our sample. In addition, χ^2 and t tests were used to compare men who reported douching to those who did not on demographic and sexual risk variables.

Results

Stage 1

Sample Characteristics—Twenty MSM participated in Stage 1. On average, they were 38 years old (SD = 13), had graduated college, and had a mean annual income of USD \$30,000. We emphasized the recruitment of ethnic minorities to maximize the sample's diversity (5 Latinos, 4 African Americans, 2Asian/Pacific Islanders, and 9 Whites).

Douching before sex—Fourteen participants (70%) reported douching; 12 douched in preparation for sex, half of them regularly. Men douched before sex mainly for hygiene (see Table 1), many perceived sex was more pleasurable if they had cleansed beforehand. Two men specifically linked douching to *unprotected* RAI, in which case cleanliness was more

important. Some men felt RD reflected consideration for their partner, at times leading them to forego RAI if they had not douched. One man said that if he were caught "off guard" and had not douched, he would inform his partner so that he could decide whether to have intercourse. Some men had been rejected for not being clean, while others had more forgiving partners.

Douching after sex—Five out of 14 men used douches after sex for hygiene and to avoid leakage. Men thought that douching <u>after</u> sex provided STI protection. For some men, douching decreased guilt of engaging in unprotected RAI. When a condom was used or the partner had not ejaculated inside them, participants reported being less likely to douche.

Solutions used—Fleet® enemas, water, or soapy solutions were used applied with enema bottles or plastic or rubber bulbs. A few participants reported that enemas resulted in bloating and discomfort

Some did not douche—Those who did not douche gave as reasons not liking it, experiencing uncomfortable feelings following douching and, in one case, "liking it dirty." One man mentioned not douching because he was aware it could be harmful.

Poor adherence to request not to douche—Although men reporting regular (twice a week or more) RD were excluded from Stage 1 of the study, and men were instructed *not* to douche during the volume escalation trial, eight of the 14 participants reported douching on at least one RAI occasion, either beforehand or afterwards. The main reason for RD during the trial was hygiene, at times per the partner's request due to leakage caused by the placebo gel.

Having observed that, regardless of the request not to douche, men did it anyhow, we removed the douching exclusion criterion for Stage 2 and did not ask participants to abstain from douching.

Stage 2

Sample Characteristics—Participants in Stage 2 were 105 men, on average 39 years old (SD = 10.45), and had completed high school. Two-thirds were employed, having a median income in the \$10,001-\$20,000 range. Two-thirds identified as White, and three-quarters identified as gay.

Sexual Behavior—All but two participants reported having had at least one male sexual partner in the prior two months with whom they had engaged in RAI; 83 (75.2%) men had had unprotected RAI. On average, participants reported having 4.31 (SD = 5.12) male sex partners and engaging in 10.70 occasions (SD = 13.81) of RAI, slightly more than half of them unprotected (M = 6.36, SD = 12.52), during the prior two months; 78% of participants also reported having insertive anal intercourse (IAI), with 63 men (60%) doing it unprotected. On average, participants had 6.37 (SD = 10.58) IAI occasions and 2.16 (SD = 2.28) partners. Sixty percent of IAI occasions were unprotected. Forty percent of participants reported having an HIV positive male partner or not knowing the HIV status of a male partner with whom they engaged in unprotected anal sex. Men who douched in the past 6 months were compared to those who did not on all demographic and sex risk variables. No significant differences were found.

Douching Practices—Half of the sample (N = 54; 51%) reported using RD in the past six months, generally in more than one occasion (M = 14.20, SD = 14.45, Md = 1). The

most common places to do douche were the toilet (N= 22; 40.7%) or shower/tub (N= 31; 57.4%).

Most men douched in preparation for sex (N= 49; 91%; see Table 2). Over two-thirds of men who douched before sex did it frequently (N= 18; 36.7%) or always (N= 20; 40.8%). The mean age of onset for douching prior to sex was 28 years (SD= 9.51; Md= 25). On average, men douched about two hours prior to sex (SD= 2.91; Md= 1 hour) because they wished to be clean (N= 38; 77.6%), were encouraged by their partner (N= 15; 30.6%) or had discussed it with a friend (N= 13; 26.5%).

Approximately half of men who reported douching had used RD following sex (N= 26; 48%). Two-thirds of these men did it always (N= 7; 26.9%) or frequently (N= 10; 38.5%). The mean age of onset for douching following sex was 28 years (SD= 11.18; Md= 25). These men douched on average about 1 hour after sex (SD= 1.72; Md= 30 minutes) to clean themselves (N= 23; 88.5%) or to prevent getting STIs from their sex partners (N= 4; 15.4%) (see Table 2).

Douching Products and Application—Of the 54 men who douched in the past 6 months, 42 (77.8%) used a hose apparatus and 33 (66.1%) a pre-packaged bulb apparatus. Among the former, 32 (76.2%) used a non-disposable douche or enema bag system, and 26 (61.9%) used a showerhead hose and nozzle. A few men used a portable rubber or vinyl hose attached to a sink ("sinker"; N = 6; 14.3%). Most men reported running water for an average duration of approximately 6 minutes (SD = 9.7).

Among the 33 men who used a pre-packaged bulb apparatus, 28 (84.8%) used an over-the-counter disposable enema product, 17 (51.5%) a re-usable bulb enema, and 7 (21.2%) some other kind of apparatus. More than half of the 33 participants who used pre-packaged products indicated they douched more than once per event (N= 19; 57.6%).

Men douched standing (N= 19; 35.2% of 54 men who douched), kneeling (N= 15; 27.8%), squatting or seated over a toilet or tub (N= 16; 29.6%), or lying on their sides (N= 4; 7.4%); 9 men (16.7%) inserted the applicator 1 inch into the rectum, 19 men (35.2%) inserted it between 1 to 2 inches, 14 men (25.9%) inserted it 2 to 3 inches, and 12 men (22.2%) more than 3 inches. Twenty-three men (42.6%) reported cramps or discomfort when douching, yet most experienced it infrequently (N= 19; 35.2%). One participant noted injury due to the use of a rectal douche or enema product.

Discussion

This study explored behavioral aspects of RD in association with sexual intercourse among MSM who engage in sexual risk behaviors. Douching behavior appears to be very ingrained among those who practice it as evidenced by the refusal to abandon it among participants in Stage 1 of our study (who were asked not to douche), those who reported douching despite side effects (like cramps), and those who reported abstaining from intercourse if they had not douched. Using mixed (qualitative and quantitative) methods, we found that half of HIV-uninfected men in our sample who had RAI douched frequently or always prior to RAI, mainly for hygiene and the relaxation experienced when feeling clean and able to enjoy sex with a partner. Consideration for one's partner, who may react negatively to exposure to feces, is also an important factor, and men who have RAI report that their partners support, encourage, and at times demand that they douche. Half of the men who douched did it after sexual intercourse, mainly for hygiene but in some cases also believing it decreased chances of acquiring STIs.

The implications of these douching practices are twofold. First, if douching behavior can have negative health effects but is unlikely to be abandoned, as has been the case among women who use vaginal douches, it is of paramount importance to continue identifying douches likely to result in less harmful side effects.9 Studies are currently underway to establish the mucosal effect of hypo-osmolar, iso-osmolar, and hyper-osmolar rectal douches (Craig Hendrix, personal communication 1-26-09). Findings should be used to educate MSM on the safest products.

Second, if douches that incorporate HIV/STI preventive agents can be developed, RD prior to or following sexual acts can become an important alternative prevention tool. A liquid vehicle carrying a microbicidal agent may be well-suited for difficult-to-reach areas of the intestine, and provide more extensive mucosal coverage than a gel. Furthermore, a microbicidal douche (MD) could precede the use of microbicidal lubricant gel during sex to increase protection. To reshape an existing behavior to which some men strongly adhere, like douching, by suggesting the use of one type of douche over another may be more successful than trying to move MSM to engage in behaviors they never practiced before or those they resist (e.g., condom use). The fact that douching occurs, on average, two hours before the anticipated sexual encounter or 1-2 hours after the encounter means that, in most cases, douching does not compete in the "heat of the moment" with ongoing sexual behavior. Furthermore, although different types of douching apparatus are used, prepackaged bulb apparatus or disposable enemas appeared to be the most popular, again a good omen for the eventual development of microbicidal douches. Nevertheless, habitual behavioral patterns should be carefully analyzed to understand how they could impact the use of a potential MD. For example, participants used more than one douche application in preparation for sex; this raises questions about dosage for douches containing microbicides (if one application is recommended, would three applications result in overdose?). Maybe a solution would be to use an MD after using a safe douche for cleansing purposes, as the last step of the pre-sex preparation process. Another issue highlighted in our results is that the nozzle of the douching device may be introduced up to several inches into the rectum. Given that the rectal epithelium consists of a single layer of columnar or cuboidal epithelial cells that may be vulnerable to abrasion, could manipulation of the douching device result in mucosal damage that may facilitate viral entry? This issue needs to be explored.

The results of our study should be taken with caution. First, ours was a sample of volunteers living in an urban setting (Boston, MA) who participated in a microbicide study not specifically design for the study of RD. Findings of this study may not be generalizable, yet they are similar to another sample of urban MSM recruited in New York City at about the same time.14 Since urban centers are the localities where the highest incidence of HIV is found, evidence of widespread RD by MSM living in those areas underscores the need to explore their HIV prevention potential. A much larger study with a target N of 850 is currently underway with samples recruited both in the East and West Coasts (Pamina Gorbach, personal communication, 5-10-09); this study will cast some light on the generalizability of our results.

Second, individuals with frequent RD were excluded in Stage 1, thus curtailing our qualitative exploration of the higher end of the spectrum. However, Stage 2 prevalence estimates include this portion of the population. Finally, men were on average in their late 30's, had a college education and earned between \$10,000 and \$30,000 in annual income; generalizability of findings to other samples of MSM is unknown. As vaginal douching practices among women vary across racial/ethnic and socioeconomic status,19 interethnic differences in RD practices among men need to be studied.

The relentless incidence of HIV among MSM in the US20 documents that sexual risk behavior continues to exist, despite a quarter of a century of condom promotion. Biomedical and behavioral strategies to decrease HIV/STI incidence and the promotion of means of protection other than condoms are urgently needed for sexually active MSM. The development of douches with less harmful biochemical properties and protective properties may decrease the risks of HIV/STI acquisition. Clearly, not every person engaging in RAI will douche, nor will people who use douches use them every time they have anal intercourse. Yet, if we are ever going to control the HIV epidemic, it will be by increasing the availability of a wide array of behavioral and medical prevention tools that match the diversity of the populations who must adopt them.

Acknowledgments

We thank all the participants who contributed their time and effort to participate in this study. We also thank William O'Brien for his efficient coordination of the study and Rodney Vanderwarker for logistic support.

This research was supported by a grant from the NICHD (R01 046060-01), Principal Investigator: Alex Carballo-Diéguez, Ph.D. Dr. Bauermeister was supported by a training grant from the National Institute of Mental Health (T32 MH19139, Behavioral Sciences Research in HIV Infection; Principal Investigator: Anke A. Ehrhardt, Ph.D.). This research was also supported by a center grant from the National Institute of Mental Health to the HIV Center for Clinical and Behavioral Studies at NY State Psychiatric Institute and Columbia University (P30-MH43520; Principal Investigator: Anke A. Ehrhardt, Ph.D.). The content is solely the responsibility of the authors and does not necessarily represent the official views of NICHD or the NIH.

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 $\label{eq:Table 1} \textbf{Table 1}$ Timing and reasons for douching, and products used, in a sample of N=20 MSM

Doughing Defens Core	Ī
Douching Before Sex:	
Preparation for sex	Det 100, 50 years old
Before I left home, I had used a douche, and I applied some typical, like, K-Y lubricant, anally.	Ppt 100, 59 years old, white
If I'm out hunting for anal sex, I would cleanse myself by using a douche	Ppt 105, 26 years old, Asian
What leads me [to use an enema]? Oh that I know that I'm purposely going to meet with somebody for that [If] I definitely know that I will be having some kind of intercourse that night, I will definitely use an enema.	Ppt 107, 30 years old, Latino
If I knew ahead of time I would [douche], yeah	Ppt 110, 57 years old, white
Because we're preparing ourselves for anal sex in that sense	Ppt 119, 37 years old, African-American
If I know I'm going to be bottoming, I will always douche. And that's the only time I douche Well, a bottom has to really prepare beforehand.	Ppt 122, 43 years old, white
If I suspect it's going to be rough night or a rough and long night, I will most definitely do it	Ppt 123, 23 years old, African-American
If I'm anticipating a date or if I'm anticipating having anal sex with my partner uh before the sexual intercourse would occur, do the enema.	Ppt 126, 43 years old, African-American
Hygiene	
Mostly because I want to be clean inside because with anal sex, you could have some fecal matter.	Ppt 100, 59 years old, white
I think it would just make the whole experience more pleasurable More hygienic and more considerate on my part.	Ppt 110, 57 years old, white
There was kind of the cleanliness issues.	Ppt 111, 23 years old, white
I guess we don't want to pull out and see shit, feces I would say, in that sense.	Ppt 119, 37 years old, African-American
I am very bottom. I like to present my bum very clean.	Ppt 120, 37 years old, Latino
Generally a good bottom is someone who's very, very clean, who douches and is is hygienically a a good bottom would be someone who's douched out so well that you would never have any dirt or mud or whatever comes out.	Ppt 122, 43 years old, white
Foregoing sex rather than risking messiness	
I would not let a man um bareback nude in other words, fuck me without a condom, unless I had douched.	Ppt 122, 43 years old, white
Partner Rejection/Lack of rejection	
The guy that I've been sleeping with lately, he doesn't mind it that much if I'm not douchedHe's not like, "oh clean up yourself," I guess, which is fine with me because I think it's very unpleasant and uncomfortable [to douche].	Ppt 107, 30 years old, Latino
There's been a couple of people that I've been with that have insisted that I douche before they have sex with me because they get turned off at the smell of any kind of fecal matter, which I understand perfectly wellwe had had a problem with my having too much fecal matter there and they said oh, then they get turned off and then they stop having anal sex.	Ppt 112, 55 years old, white

Danakina Bafana Cam	Ī
Douching Before Sex:	
Preparation for sex	
Douching After Sex:	
Hygiene/Reduce leakage	
I have only started to do that recently. I usually use like a soapy water solution after I've had anal sex with the guy that doesn't use a condom that I feel [inaudible] the only reason why I do it is because I don't want to smell fishy. [laugh]	Ppt 112, 55 years old, white
Um, yeah. If I got fucked and I was getting ready to go out to a bar or go out to dinner then I want to get that shit out of me because I don't want it dripping out of ass.	Ppt 118, 56 years old, African-American
Perception of protection after sex	
I did a Fleet enema when that guy raped me that time, the very next day because I was so terrified that there might have been some health issues especially where I really bled profusely after that attack and I was very upset and nervous about possibly contacting HIV. So I bought a Fleet enema thinking that that would be safe to clean myself out and to get anything in there out of thereI feel very anxious. That's why I like to douche when I don't really know the person that well, and I've had anal sex I feel a little guilty. I really do. It's like, yeah it felt good at the time, but now what, now you're going to have to worry about thismaybe I've increased my safety factor a little bit doing that [after sex]	Ppt 112, 55 years old, white
because he did it without a condom, I douched after we finished	Ppt 118, 56 years old, African-American
I guess a part of me thinks that that if there's anything that's transmissible, that might help to clean things out so that I'll be less likely to get something.	Ppt 122, 43 years old, white.
After receiving ejaculate	
If they ejaculate inside me, I will use a douche, when we're finished. If they don't ejaculate, I may or may not. It depends on how I feelIf he's wearing a condom, I do not douche after we finished	Ppt 122, 43 years old, white
Types of Douche Products Used	
I only use the water to wash it	Ppt 102, 33 years old, Asian
I actually recently just bought an enema bottle	Ppt 105, 26 years old, Asian
I actually have a little bottle that I use, fill it with water and some soap in kind of solution, and I clean it outI also have bought like a Massengill douche once, a couple times, after sex, unprotected sex, thinking that that's going to kill anything in there.	Ppt 112, 55 years old, white
So yeah, I call it, it's a little douche ball. I call it Spike. So I just clean out my ass and take a shower.	Ppt 118, 56 years old, African-American
Reasons For Not Douching	
Side effects	
I get cramps really bad if I do an enema. So I don't look forward to that because it hurtsI just think [douching] is very unpleasant and uncomfortable	Ppt 107, 30 years old, Latino
Liking it dirty	
I: Do you ever use an anal douche or enema before sex? R: No. I like it dirty.	Ppt 118, 56 years old, African-American
Perception of harmfulness	
I inadvertently used a little hydrogen peroxide and water and that caused some severe problems for about a week and a half, bleeding	Ppt 112, 55 years old, white

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Douching Before Sex:

Preparation for sex

and loose stools and I was really upset and was probably a result of all that hydrogen peroxide going up there and doing a little damage to the rectum and stuff.

I basically don't use it now because of information about some increased risk of transmission.

Ppt 124, 39 years old, Latino

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 Table 2

 Prevalence and motivations for douching prior to and after sex among men who have sex with men

		N(%)
Douching in Preparation for Sex	(N = 49)	
Frequency of Douching		
Infrequently		11(22.4%)
Frequently		18(36.7%)
Always		20(40.8%)
Reasons for Douching Prior to Sex ^a		
To be clean		38(77.6%)
Sex partner suggested it		15(30.6%)
Talked about it with friends		13(26.5%)
Douching following Sex	(N = 26)	
Frequency of Douching		
Infrequently		9(34.6%)
Frequently		10(38.5%)
Always		7(26.9%)
Reasons for Douching ^a		
To be clean		23(88.5%)
To prevent getting any STIs/HIV		4(15.4%)
Sex partner suggested it		2(7.7%)
Talked about it with friends		2(7.7%)

 $^{^{\}mbox{\it a}}_{\mbox{\it Participants}}$ were allowed to check all that applied.