Rectal Douching is not Associated with Incident Rectal Gonorrhea or Chlamydia among Men Who Have Sex with Men

Emma Chrzanowski

A thesis

submitted in partial fulfillment of the

requirements for the degree of

Master of Public Health

University of Washington

2024

Committee:

Christine Khosropour

Lisa Manhart

Program Authorized to Offer Degree:

Epidemiology

University of Washington

Abstract

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Emma Chrzanowski

Chair of the Supervisory Committee:
Christine Khosropour
Department of Epidemiology

Prior studies have identified an association between rectal douching and prevalent rectal *Neisseria gonorrhoeae* (GC) and *Chlamydia trachomatis* (CT), but few studies have examined associations with incident infections.

We implemented a case-crossover study nested within the ExGen study, a 48-week cohort study conducted in Seattle, Washington, 2016-2018. Each week, ExGen participants completed a survey and self-collected rectal specimens, which were tested for CT and GC via nucleic acid amplification testing (NAAT) at the end of the study. We identified individuals who had an incident rectal GC or CT infection, defined as two consecutive weeks of a positive NAAT. For each individual, we selected 1 case-week (defined as the first week of an individual's first incident rectal GC or CT infection) and 2 randomly-selected control-weeks (defined as weeks where the participant tested negative for rectal GC or rectal). We used multivariate conditional logistic regression to estimate the adjusted odds ratio (aOR) and 95% confidence interval (CI) for the association between douching and rectal GC/CT, adjusting for condomless receptive anal sex (RAS) events in the past week and concurrent GC or CT infection.

There were 140 individuals in ExGen. Our analytic sample comprised 17 GC case-weeks and 34 matched GC control-weeks, and 22 CT case-weeks and 44 matched CT control-weeks. Participants reported douching during 64.7% of GC case-weeks and 70.6% GC control-weeks (aOR=0.55; 95% CI=0.11-2.80). Water was used during 91% of case-weeks and 96% of

control-weeks in the GC analysis. Douching was reported at a nearly identical frequency among CT case-weeks (45.5%) versus CT control weeks (47.7%) (aOR=1.16; 95% CI=0.27 – 5.07). Water was the only douching solution reported among participants in the CT analysis.

Water-based douching does not appear to increase the risk of incident rectal GC/CT.

Introduction

Rectal *Neisseria gonorrhoeae* (GC) and *Chlamydia trachomatis* (CT) infections are commonly diagnosed among clinic-attending men who have sex with men (MSM). Pooled data from sexual health clinics in the United States (US) demonstrate that the prevalence of rectal GC and CT among MSM are approximately 12% and 13%, respectively.[1] Because the majority of rectal GC/CT cases present asymptomatically and are only detected through screening, they likely contribute to sustained community transmission of GC/CT.

Rectal douching is a common sexual health practice that MSM engage in prior to receptive anal sex (RAS). Rectal douching involves inserting a liquid into the rectum in order to clean the rectum, which may occur before sex (e.g., to remove feces) or after sex (e.g., to remove ejaculate). The primary reason cited for engaging in rectal douching is that it promotes cleanliness and reduces sexually transmitted infection (STI) acquisition.[2,3] However, rectal douching may actually lead to the degradation of the rectal epithelium (via enema solutions) ultimately facilitating STI acquisition.[4,5] Indeed, a 2019 meta-analysis found that rectal douching may increase the odds of rectal GC/CT by 3-fold.[6] However, the majority of previous studies are limited by an inability to determine temporality of douching relative to a rectal infection and an inability to tease apart whether rectal douching itself actually increases the risk of acquiring rectal GC/CT, or rather that people who douche may be more frequently engaging in RAS and are thus at greater risk of rectal GC/CT.[4] Therefore, the impact of douching on rectal STIs remains an unanswered question.

We have previously reported on the primary outcomes of the “ExGen Study”, a longitudinal cohort study of MSM that employed weekly behavioral data collection and rectal GC/CT testing.[7] The ExGen study provides a unique and methodologically-rigorous opportunity to resolve the controversy of the role of rectal douching in increasing STI risk. The specific aims of this study are to evaluate the relationship between rectal douching and incident rectal GC/CT among a cohort of MSM.

Methods

Study Design, Population, and Setting

This is a case-crossover study nested within the "ExGen Study", a prospective, 48-week cohort study designed to describe the incidence and duration of rectal and pharyngeal GC and CT; ExGen procedures have been previously described.[7-9] A total of 140 MSM were enrolled in the ExGen Study. Participants were recruited in December 2016 through March 2018 from the Public Health - Seattle and King County (PHSKC) Sexual Health Clinic (SHC) and the University of Washington's Center for AIDS Research (CFAR) patient registry. ExGen participants were male sex at birth ≥18 years old who reported sex with men, spoke and read English, had internet access, and reported engaging in receptive anal intercourse in the last 12 months and had performed oral sex within the last 2 months. Additionally, participants must have reported at least one or more of the following: (1) diagnosis of gonorrhea, chlamydia, or syphilis in the past 12 months, (2) use of methamphetamine or amyl nitrite ("poppers") in the last 12 months, and (3), having more than two sexual partners in the past 2 months or more than 5 sexual partners within the last 12 months. Study procedures were reviewed and approved by the University of Washington Institutional Review Board. Participants completed written informed consent.

Data Collection and Measures

At enrollment, participants completed an electronic survey which included detailed questions on demographics, STI history, HIV serostatus and duration of HIV care, and sexual behavior. Participants were also tested for rectal and pharyngeal GC and CT, syphilis, and HIV if the participant had not been previously diagnosed with HIV. Those testing positive for any STI at enrollment were treated per clinic standard-of-care and asked to delay starting weekly study procedures (e.g., weekly surveys and specimen collection) until two weeks after GC treatment was completed and three weeks after CT treatment was completed.

Each week for 48 weeks, participants were sent an electronic survey which asked questions about their sexual behavior (including number of sex partners, types of sex [e.g., oral,

receptive/insertive anal], condom use, and douching), symptoms, and antibiotic use in the past week. The specific survey questions used in this analysis are described below. Each week participants also self-collected a rectal specimen using the Aptima multitest collection system (Hologic, Inc., San Diego, CA). Participants returned their specimens to study staff weekly via the US Postal Service. Aptima specimens for GC and CT testing have been shown to be stable up to 84 days and in ambient temperatures between 2˚C and 36˚C.[10] When specimens were returned to study staff, they were stored at -80˚C until the participant had completed the entirety of the study. At the conclusion of a participant's participation, specimens were tested for GC and CT via nucleic acid amplification testing (NAAT) using the Aptima Combo 2 assay (Hologic, Inc., San Diego, CA) on the fully automated Panther system.

Rectal douching was the primary exposure in this analysis. Douching information was obtained from the weekly survey which participants completed the same week that they collected a rectal specimen. The specific question asked was: "*Did you do any of the following BEFORE having sex since your last diary entry?"* with "enema/rectal douching" as a response option. Participants answering "Yes" to the douching question were then asked to indicate the type of enema/rectal douche solution that they used ("check all that apply" with a fixed list plus a write-in option).

Definition of Cases and Controls

In this case-crossover design, cases and controls were defined as periods of time (i.e., case-weeks and control-weeks) that were contributed by the same individual.[11] Case-crossover designs minimize the risk of confounding since both measured and unmeasured "fixed" participant characteristics are identical for case-weeks and control-weeks.[12] For this study, we conducted separate analyses for rectal GC and rectal CT. Below we refer to GC/CT for simplicity and not to infer a combined outcome.

We defined a participant's case-week as the first, and only, week of their first incident rectal GC or CT infection. Consistent with our previously-published primary analyses for this

cohort, we defined an incident event of rectal GC or CT infection as two consecutive weeks of a NAAT-positive rectal specimen.[7-9] We chose this approach because we believe that single weeks of a positive NAAT result may not represent a “true” infection, but rather detection of nucleic acid from non-variable organisms. Control-weeks were drawn from the same participant that contributed case-weeks in a 2:1 ratio. Control-weeks were weeks where the participant contributing the case-week had a negative test result for rectal GC (in the GC analysis) or rectal CT (in the CT analysis); weeks where a participant did not return a specimen were not eligible control-weeks. To maintain consistency with a unidirectional design, control-weeks were randomly selected from weeks preceding case-weeks.[11] This was done to ensure that the douching associated with a control week occurred prior to the incident infection (i.e., that douching was not influenced by their infection).

Statistical Analysis

All analyses were conducted for rectal GC and CT separately. For our analysis estimating the association between douching and rectal GC/CT, we report the proportion of case-weeks and control-weeks where the participant reported douching use in the prior week. We used conditional logistic regression to estimate the odds ratio (OR) and 95% confidence interval (CI) for the association between douching and rectal GC/CT. We report unadjusted ORs and adjusted ORs (aORs) from multivariate conditional logistic regression models adjusted for number of condomless RAI episodes in the past week and concurrent rectal GC or CT infection (e.g., adjusted for rectal GC infection in the rectal CT analysis and vice versa). Because case-weeks and control-weeks are drawn from the same individual, there were no adjustments for demographic or other “fixed” characteristics (e.g., age, enrollment STI diagnosis). We also describe the distribution of types of douching solutions reported during case-weeks and control-weeks.

All analyses were conducted on a de-identified dataset using R version 4.2.1. We considered statistical significance at an alpha<0.05.

Results

Of the 140 participants enrolled in ExGen Study, 18 participants had ≥ 1 incident rectal GC infection and 24 participants had ≥ 1 incident rectal CT infection. One participant with rectal GC and two participants with rectal CT did not have two eligible control-week periods and were subsequently excluded from this analysis. Therefore, our final analytic sample for the GC analysis included 17 GC case-weeks and 34 matched control-weeks, and for the CT analysis included 22 CT case-weeks and 44 matched control-weeks.

Enrollment characteristics and weekly survey data are included in Table 1. Because case-and-control-weeks are drawn from the same individual, the distribution of enrollment characteristics between case-weeks and control-weeks are identical. Participants included in the GC analysis had a mean age of 37, 82% were living with HIV, and over 80% had been diagnosed with a bacterial STI in the 12 months prior to enrollment. The median number of sex partners in the past week was the same for GC case-weeks and control-weeks (3 partners), but participants reported a slightly higher number of condomless RAS acts in the past week during control-weeks compared to case-weeks (2.0 vs 1.5 acts, respectively), although not statistically significant. Among participants in the CT analysis, the mean age was 37, 50.0% had been previously diagnosed with HIV and 86.4% had a bacterial STI diagnosis within 12 months of study enrollment. The median number of sex partners in the prior week was 2 for both case-weeks and control-weeks, whereas the median number of condomless RAI acts in the prior week was higher for control-weeks (1.0 acts) versus case-weeks (0.0 acts) although not significant.

Participants reported douching during 11 (64.7%) of 17 GC case-weeks and 24 (70.6%) of 34 GC control-weeks (OR=0.65; 95% CI=0.13-3.16) (Table 2). After adjusting for the number of condomless RAI acts in the past week and rectal CT test result, we observed a non-significant inverse association between douching and incident rectal GC (aOR=0.55; 95% CI=0.11-2.80). In the GC analysis, the majority of participants reported using water for

douching: during weeks when participants reported douching, water was used during 10 (91.0%) of 11 case-weeks and 23 (95.8%) of 24 control-weeks. Fleets, a sodium phosphate agent, were used during 1 (9.0%) of 11 case-weeks and 1 (4.2%) of 24 control-weeks.

Douching was reported at a nearly identical frequency among CT case-weeks compared to CT control weeks (45.5% vs. 47.7%, respectively). We did not observe a statistically significant association between douching and incident rectal CT (aOR=1.16; 95% CI=0.27 – 5.07) (Table 3). Water was the only douching solution reported among participants in the CT analysis.

Discussion

In this case-crossover study, we found that rectal douching was a relatively common practice (reported during 45%-71% of weeks) but was not significantly associated with acquiring rectal GC or CT. This is in contrast to most other studies. A 2019 meta-analysis of 8 studies found that rectal douching increased the odds of rectal GC or CT infections by 3-fold.[13] Studies that have been published since that meta-analysis have also identified significant associations between rectal douching and rectal STIs.[3,14,15] Only two studies have found that rectal douching is not associated with rectal GC/CT [16,17], but even those studies identified a positive association between douching and rectal GC/CT, just not a statistically significant one.

We postulate several reasons why our findings did not align with other studies. First, the majority of studies exploring this association have not been able to determine whether rectal douching preceded or followed acquisition of rectal STIs. Most prior studies have been cross-sectional [3,15,18,19] whereby participants are asked about douching at the same time that they were tested for (or asked about) rectal STIs. Therefore, it is impossible to tease apart whether the participant acquired an STI before or after douching. Related to this, many prior studies asked participants about douching in general and not about douching *prior to* sex. Longitudinal studies have attempted to address this limitation of temporality. In a 2018 longitudinal study

from Hassan and colleagues, information on douching frequency was collected at baseline (past 30 days) and participants were tested for rectal GC/CT five times over the subsequent 48 weeks. The investigators found the douching was associated with incident rectal infection However, they did not collect information on douching longitudinally[20], so it is unclear whether douching at baseline still had an impact on rectal STI acquisition months later. Blair and colleagues also conducted a longitudinal study. Participants in that study returned to clinic every 6 months at which time they were asked about douching in the past 30 days and tested for rectal STI. This study also noted a significant association between douching and rectal STI, but it is unknown whether the participant acquired the STI prior to the time period for which they were reporting douching.[14] Our study design attempted to mitigate this limitation in two ways. First, each week participants were asked about rectal douching in the past week and they self-collected rectal specimens for NAAT testing. This allowed us to identify the temporality of douching relative to an incident infection. Second, we asked participants specifically about whether or not they douched *prior to* sex, to ensure we were accurately capturing the relevant exposure.

Second, the results of prior studies may be confounded by frequent RAS. Rectal douching may be more common among individuals frequently engaging in RAS – and because people who engaged in RAS are at greater risk of acquiring rectal STIs – it may be that rectal douching is a marker of frequent rectal exposure rather than a risk factor. Prior studies have attempted to address this by including RAS or number of partners as an adjustment factor (confounding factor) in multivariate modeling, but this likely does not entirely mitigate the confounding. Our case-crossover design was well-suited to address this confounding by examining the association between douching and rectal STI within the same person, which allowed us to control for the fact that those individuals who are more likely to douche may be those who have more RAS. Additionally, we adjusted for RAS acts in the prior week to account for differences in rectal exposure between case-weeks and control-weeks.

Third, our findings may differ from other studies because our exposure of douching in the past week may not accurately capture the risk of douching. It is possible that frequency of douching is a more appropriate marker of douching risk than a simple “yes/no” in the past week. In the aforementioned study by Hassan and colleagues, douching weekly or more was 3.59 times as likely among individuals who reported a positive rectal infection than among those who did not douche.[20] It is also possible that our exposure of douching in the past week is too proximal to the acquisition of rectal STIs. The main hypothesis around rectal douching being a potential risk factor for incident rectal GC/CT infections is that rectal douching disrupts the endorectal epithelium thus damaging the mucosal membrane in the rectum and impedes the mobilization of immune cells to the area.[4] This process may require a time frame longer than one week and likely occurs more severely with a greater frequency of douching.

Fourth, the type of douching solution used in our studies relative to others may be a reason why our findings differ from other studies. However, water-based enema solutions, which were reported by the vast majority of our study participants, are also the most commonly-reported solution in most other studies, including those that identified an association between rectal douching and rectal STIs.[18,19,21] Indeed**,** tap water and soapsud-based enema solutions appear to yield the highest surface epithelium loss compared to polyethylene glycol electrolyte solutions (PEG-ES).[5]

Given that our study’s findings differ from most other studies, but was also one of the more methodologically-rigorous studies to be conducted on this topic, we believe that it is still fair and reasonable to provide messaging to the MSM community that douching may be a risk factor for rectal STI. Our results should not be used to propagate the currently circulating misinformation that rectal douching *prevents* STI.[19,22] We believe that the most helpful messaging moving forward is to promote the types of douching solutions that have been shown to be the least disruptive to the rectal epithelium (e.g., PEG-ES)[5] as well as considering making these types of “safer” douching solutions freely available in sexual health settings, in the same

way that condoms and lubricant are. At the same time, we recognize that the context and discourse in the MSM community around douching is vastly complex and extremely personal.[23] It is important to contextualize douching in a diverse sexual culture and recognize that survey questionnaires may be unable to capture the full extent of an individual's sexual health practices.

Our study has several strengths. We used a case-crossover design to reduce confounding of measured and unmeasured "fixed" variables. The weekly rectal STI testing and rectal douching data collection limited recall bias, provided an objective measure of incident infection, and allowed us to determine if douching occurred prior to acquisition of the STI. Our findings should also be interpreted in the context of other limitations. First, there are still unmeasured confounders that are time-dependent that we were unable to capture. Second, weeks where participants did not complete the weekly survey or did not return self-collected rectal specimens were not reflected in this analysis. Insofar as those weeks may be different than those included, our results may be biased. Third, recall bias may have impacted participants' ability to report on their exposure and sexual behaviors; however, the fact that data were collected every week minimized the potential for recall bias. Additionally, the relatively small number of incident infections limited our ability to identify statistically significant differences among study participant case-weeks and control-weeks. Finally, these results were from a single cohort of MSM in Seattle and our results may not be generalizable to other settings.

Overall, we did not observe an increased risk of water-based rectal douching on incident rectal GC/CT infections in MSM. Unfortunately, our findings contribute to – rather than resolve – the controversy surrounding whether or not douching is a potentially harmful practice. A better understanding of the mechanisms of douching products and the impact of the longer-term frequency of use will help to develop guidance for the MSM community about this practice.

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Table 1: Demographic, clinical, and behavioral characteristics of MSM at enrollment and as reported in the weekly survey and specimen testing, stratified by case/control status and incident rectal GC and CT.

	Incident Rectal GC		Incident Rectal CT	
Enrollment Characteristics	Case-Weeks (N = 17)	Control-Weeks (N = 34)	Case-Weeks (N = 22)	Control-Weeks (N = 44)
Age (years), mean (range)	37 (21 – 75)	37 (21 – 75)	37 (20 – 73)	37 (20 – 73)
Race, n (%)				
White/Caucasian	15 (88.2)	30 (88.2)	21 (95.5)	42 (95.5)
Black/African American	1 (5.9)	2 (5.9)	-	-
Asian/Pacific Islander	-	-	1 (4.5)	2 (4.5)
Another race not listed	1 (5.9)	2 (5.9)	-	-
Hispanic/Latino, n (%)				
Yes	3 (17.6)	6 (17.6)	3 (13.6)	6 (13.6)
No	14 (82.4)	28 (82.4)	19 (86.4)	38 (86.4)
Living with HIV, n (%)				
Yes	14 (82.4)	28 (82.4)	11 (50.0)	22 (50.0)
No	3 (17.6)	6 (17.6)	11 (50.0)	22 (50.0)
Enrollment STI diagnosis, n (%)				
Syphilis - early or late	2 (11.8)	4 (11.8)	1 (4.5)	2 (4.5)
Pharyngeal gonorrhea	1 (5.9)	2 (5.9)	0 (0)	0 (0)
Rectal gonorrhea	2 (11.8)	4 (11.8)	1 (4.5)	2 (4.5)
Urethral gonorrhea	0 (0.0)	0 (0.0)	0 (0)	0 (0)
Pharyngeal chlamydia	0 (0.0)	0 (0.0)	1 (4.5)	2 (4.5)
Rectal chlamydia	2 (11.8)	4 (11.8)	6 (27.3)	12 (27.3)
Urethral chlamydia	0 (0.0)	0 (0.0)	0 (0)	0 (0)
Criteria for Study Entry[†], n (%)				
Bacterial STI diagnosis <12 mo.	14 (82.4)	28 (82.4)	19 (86.4)	38 (86.4)

Meth or popper use	3 (17.6)	6 (17.6)	2 (9.5)	4 (9.5)
Number of Sexual Partners	15 (88.2)	30 (88.2)	19 (86.4)	38 (86.4)
Median number of sex partners in the past 2 months, (IQR)	12 (6 – 15)	12 (6 – 15)	8.5 (5 – 12)	8.5 (5 – 12)
Median number of RAI acts in the past 2 months, (IQR)	8 (4 – 10)	8 (4 – 10)	4 (2 – 9)	4 (2 – 9)
Characteristics from Weekly Survey and Specimen Testing				
Median number of sex partners in the past week, (IQR)	3.0 (2.0 – 4.0)	3.0 (1.25 – 4.0)	2.0 (0.25 – 3.0)	2.0 (1.0 – 3.25)
Median number of condomless RAI acts in the past week, (IQR)	2.0 (0.0 – 3.0)	1.5 (0.0 – 3.0)	0.0 (0.0 – 2.75)	1.0 (0.0 – 2.0)
Tested positive for rectal CT	1 (5.9)	3 (8.8)	22 (100)	0 (0)
Tested positive for rectal GC	17 (100)	0 (0)	4 (18.2)	3 (6.8)

* Demographic and clinical variables are at the time of enrollment and are identical distributions for cases and controls because case-weeks and control-weeks are drawn from the same person.

† Three study criteria for study entry are not mutually exclusive of each other

Table 2: Frequency of douching by case-week and control-week status among MSM that had an incident rectal GC infection, and the corresponding association between douching and incident rectal GC.

	Case-Weeks N (%)	Control-Weeks N (%)	OR (95% CI)	aOR* (95% CI)
Reported douching in the last week	**N = 17**	**N = 34**		
Yes	11 (64.7)	24 (70.6)	0.65 (0.13, 3.16)	0.55 (0.11, 2.80)
No	6 (35.3)	10 (29.4)	*Referent*	*Referent*

aOR, adjusted odds ratio, CI, confident interval
* Adjusted for number of condomless RAI episodes in the last week, and rectal CT test result

Table 3: Frequency of douching by case-week and control-week status among MSM that had an incident rectal CT infection, and the corresponding association between douching and incident rectal CT.

	Case-Weeks N (%)	Control-Weeks N (%)	OR (95% CI)	aOR* (95% CI)
Reported douching in the last week	**N = 22**	**N = 44**		
Yes	10 (45.5)	21 (47.7)	0.86 (0.23, 3.19)	1.16 (0.27, 5.07)
No	12 (54.5)	23 (52.3)	*Referent*	*Referent*

aOR, adjusted odds ratio, CI, confidence intervals
* Adjusted for number of condomless RAI episodes in the last week, and rectal GC test result