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Attitudes of men in an Australian male tolerance study towards microbicide use

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Abstract

Background—Vaginal microbicides are in development to provide new options for prevention of STIs. Although promoted as a female initiated product, men may influence the decision to use a microbicide and the way that it is used, so it is important to explore their views.

Methods—Men (n=36) enrolled in a 7-day, phase 1 clinical safety trial of SPL7013 Gel were interviewed pre and post-use of the gel. The trial did not include use of the gel during sex. Interviews were digitally-recorded and transcribed verbatim, and analysed using a framework approach.

Results—The men (mean age 37 years) were interested in the idea of vaginal microbicides, had little knowledge about them, and varied beliefs about how they work. They tended to assess microbicide use in relation to condoms and lubricants. Many would want a microbicide to be as effective as condoms. Participants did not anticipate difficulties discussing use with their partners. Many thought that a microbicide would be less intrusive than condoms; some anticipated that the lubricating properties might enhance sexual pleasure. Some anticipated using a microbicide with a condom or with a lubricant, and a few raised questions about the timing of use and use during different types of sexual activity.

Conclusions—No major barriers to microbicide use were found in this sample of Australian men, who anticipated being willing to use them if they are shown to be safe and effective. Our findings should help to inform the design of further studies as well as future information materials and anticipatory guidance.

Keywords

microbicides; acceptability; sexuality; males

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Introduction

Topical vaginal microbicides are being developed to provide an additional option for prevention against sexually transmitted infections (STIs), including HIV. Although correct and consistent use of condoms provides protection against transmission of STIs including HIV, gonorrhea, and Chlamydia,¹ herpes simplex,² and human papilloma virus,³ the incidence of STIs in developed countries remains unacceptably high.^{4,5} Condoms may be used incorrectly⁶ or inconsistently because of perceptions that they are difficult to discuss, interrupt sex, decrease sexual pleasure,⁷ and may break or slip off,⁸ or because people are intoxicated when they have sex.⁹ It is often difficult for women to request condom use and it has been hoped that microbicides may prove to be a protection method that they could use covertly.¹⁰ However, it is likely that men may be able to detect use^{11,12,13}, that most women would discuss use of a microbicide with their regular sex partners¹⁴, and that many men would prefer this.^{11, 15} The views of men are therefore likely to influence microbicide use,^{16,10} but have been less widely studied than the views of women.¹⁵

Communication between partners is known to influence the use of contraception and STI prevention^{17,18}, and there have been calls for microbicide acceptability studies to explore social, contextual and interpersonal factors in addition to product attributes.^{19,15} We therefore took the opportunity provided by a phase 1 male safety trial of the candidate microbicide, SPL7013 Gel²⁰ to explore in a qualitative study the attitudes of Australian men towards anticipated microbicide use with female partners.

Methods

The participants in the acceptability study were the 36 men recruited for the safety trial of SPL7012 Gel. Inclusion criteria included being HIV negative, older than 18 years, and having had sex with a woman within the past year. The men were recruited through a letter mail out, newspaper and radio advertising, and posters in universities, hospitals, and a sexual health clinic. Details of the study and candidate microbicide were given to all the men, including that the microbicide is intended for use in the vagina. The study was approved by the Alfred Hospital Human Research Ethics Committee.

Safety trial procedures

Twenty-four men received 3% w/w SPL7013 Gel, and 12 received placebo gel.²⁰ All the men were asked to apply the gel to their penis at night and allow to air dry, and to abstain from all sexual activity (including masturbation) for the seven days of the study. They were reimbursed US \$250 for their participation, which included five visits for clinical examination.

Description of the participants

The median age of the men was 34 years; range 22 to 67 years and 83% were Caucasian. Forty-four percent had had one sexual partner in the previous year, 22% had had two partners, 11% had had three partners, and the remainder of the sample had had between four and 10 partners (23%). Of those who mentioned their status, six were married, eight were in a serious relationship, and four were in a casual relationship or were "single". Two men spontaneously reported being in sero-discordant relationships (one for HIV and one for herpes simplex virus).

Acceptability study methods

Participants were interviewed by trained male interviewers using a semi-structured approach at the enrollment visit after they had been given the gel and the instructions for use, and

again at their final visit. Topics included perceptions of microbicides, criteria that might influence future use, use during sex, and discussing use with partners. Interviews were digitally recorded and transcribed verbatim. In four cases the interviewer reconstructed the conversations from memory and notes because recording failed; an additional three transcripts were incomplete. Data were analysed following a 'framework' procedure similar to that described by Ritchie and Spencer.²¹ Transcripts were read several times to become familiar with the data. The three researchers identified initial themes through consensus. Each transcript was coded and the coding scheme was refined as new themes emerged. The data were organized and analysed by theme, with points summarized and illustrated with verbatim quotes. The pre-use interviews tended to be short and there was no suggestion of any pattern of changed opinions comparing pre- and post-use interviews. For this reason we did not link the pre and post-use interviews for the analysis. The placebo gel could not be distinguished from the SPL7013 Gel so the transcripts were not analysed separately.

Results

General perceptions of microbicides

Although more than half of these men had had more than one sexual partner in the past year and many had had more than four, many of them did not currently perceive themselves as at risk for STIs and did not use condoms. Most of them knew little about microbicides but found the idea interesting and some indicated that they took the consequences of HIV and STIs seriously: *"With HIV you are talking about your life, with other STIs you are talking about a lot of discomfort and in worse cases your life, or your reproductivity."* Men revealed varied beliefs about the mechanism of action which sometimes had implications for their confidence in the safety or efficacy of the product. Some were not sure how a microbicide might work: *"I am not sure how the thing is supposed to work, whether it is supposed to stay a moist thing on the genital organs or whether it is supposed to dry and it is supposed to be like a condom sort of arrangement."* Some were skeptical: *"I find it amazing how a gel can prevent an infection like HIV because if you get even one cell infected then it spreads throughout your whole body."* Many thought that it would form a physical barrier against HIV: *"the cream acts as a barrier which would prevent the transference of the virus, I'm not sure exactly how it does it but that is my understanding of it."* This belief was sometimes associated with concerns about efficacy: *"... with a condom it's a tangible barrier, I be worried what if being applied in the vagina what if it wasn't applied properly, or didn't cover the vagina properly"* and *"I'd be curious about dilution as well, from vaginal and seminal fluids, some women can have a lot of juices, and obviously once a guy's come there's a lot of fluid running around there."* A few talked in terms of the gel "eliminating infection". One man said: *"I guess the microbicide somehow kills the virus before it gets into the system."* which led to safety concerns: *"I wonder what else it might affect given that it's not just a gel - it's got some, it's aimed at killing viruses - or what else it might affect that should be there."*

Criteria that would influence future use

Most men said that efficacy was the most important factor that would influence whether they would suggest using a microbicide. Many said that a microbicide would need to provide at least the same protection as condoms before they would rely on it. For some men, anything less than 100% effective would not be acceptable: *"it would be like having a gun with 100 barrels and taking the bullets out of all the chambers except for 10, you know and spinning saying there you go, you want to take a chance"*. Interestingly, one man suggested that greater efficacy might be expected from microbicides than from condoms because people are used to a succession of improved products: *"Because these days things have been*

designed differently, they're all better than the previous products so I'd say it would be more effective."

Some men indicated that they would be willing to consider a product which was partially effective. Interestingly, some had assumed that a topical microbicide is intended as an adjunct rather than a 'stand alone' prevention method: *"I assume that you would be using it with something else so, I mean are you talking about if you were to use it just as is?"* One man in a long term relationship with a partner with herpes said, *"I would certainly [be] looking at alternatives for prolonged use so even if it were 50% I would use it."* Some men implied that potential advantages of microbicides over condoms might outweigh concerns about lower efficacy. One man expressed concern that microbicides might reduce condom use: *"there'd be a lot of disadvantages to the society, I suppose, because maybe people will start using it and not use condoms and there's a lot of consequences with that."*

Other men thought that microbicides might be more reliable than condoms, which can break or slip off. However, there were some concerns about the technique of application: *"from a selfish point of view if I am applying the condom to myself I know I have done everything right, where I have to trust someone else to do the application correctly."* There was also a concern about how long protection might last during sex: *"In a 24 hour period you might have sex two, three or maybe four times so that would be one important thing. How long it lasts."* Another man wanted to know how long before sex a microbicide could be applied and how this might affect efficacy.

Men indicated that safety would also influence their decision to suggest microbicide use to their sexual partner. Some men said that they would read the label on the box or check the ingredients on the internet, but others said that they would rely on government standards: *"I have sort of faith in the health system that they wouldn't release stuff onto the market that is not safe."* Other men had less confidence in over-the-counter products: *"because it's a bit of a gamble taking things off say a supermarket shelf ... you sort of rely on doctors when they give you something to take, but just getting it off a supermarket shelf, you know, you think well is this going to help me or not".* A few men indicated that they would decide about safety after a microbicide had been on the market and in use for a while. One man thought a microbicide should only be available on prescription until its safety profile was better established. Some men mentioned concerns about "allergies" and one man indicated that he would want to know specifically about potential impact on future fertility. When asked about safety for female partners, men generally viewed the partner as having the responsibility to decide for herself.

Most men in this study, many of whom did not currently perceive themselves as at risk for STIs or were not using condoms, would prefer a microbicide that provided both contraceptive and STI protection. One man was surprised that a product might be able to protect against STIs but not against pregnancy. Some men felt that a microbicide with contraceptive properties might avoid the side effects of hormonal contraception. For example, one man said: *"If I could say to my partner, look you don't have to worry about contraception, it would liberate them, I mean if there is weight gain, there are a lot of issues for contraception for your partner, so that would make life a lot better".* On the other hand there were also concerns that microbicidal gels with contraceptive properties might have harmful effects: *"Does it affect the male's ability to procreate or does it affect the female's? ... but I would rather wear a condom for a half an hour to an hour or whatever it is while having sex than have a woman take a pill that is interfering with her system for good."* Some men noted that a microbicide with dual protection would allow women to protect against STIs without indicating this motive to their partners. A few men believed that there was a need for a product which could allow conception while preventing STI transmission. Both

the man with an HIV-positive partner and the man whose partner carried herpes simplex mentioned the advantages of a microbicide that would allow conception.

Use during sex

When men were asked how they imagined the gel might affect sex they tended to view the gel favourably compared to condoms. Several mentioned that using the gel would cause less interruption than a condom because the woman could apply it before foreplay and erection and would allow sex to be spontaneous. But some thought that: *“it’s all a bit sort of, um, sterile, you know. It would sort of break the mood somewhat to get out an applicator and squeeze it on”*. One man also mentioned the benefit that: *“there wouldn’t be anything to dispose of like you would have with a condom”*. Another advantage over condoms anticipated by some men was that: *“you wouldn’t have the problem of decreasing the sensation like with condoms during sex.”*

Attitudes towards lubrication during sex and opinions about the likely lubricating qualities of the gel varied. Some men simply thought of the microbicidal gel as a lubricant *“it looked like a clear gel – like a normal lubricant.”* and tended to view this positively: *“I guess it’s a lubricant, so I guess in that way it would be positive.”* Some believed that lubrication is important for the pleasure of both men and women: *“you’ve got to have some lubrication especially with a foreskin or it becomes quite painful. I don’t know that you can ever really have too much lubrication from my perspective.”* and *“I think it could assist in lubricating the penis or the vagina prior to arousal which is always a good thing”*. However, a few men thought that the lubricant characteristic of the gel might cause loss of sensation: *“It depends on if it caused some sort of excess lubrication maybe and that could cause a loss of sensation, I’m not sure.”*

When they applied the gel to their penis (which will not be the recommended method of application) many men thought the gel was sticky and dried quickly. This led to a concern that it might cause friction during sex that would be uncomfortable or reduce pleasure: *“...it dried into this sort of coating. And that didn’t take long - standing in front of just a draught or fan it dries. So I imagine that it may cause complications while you are in the act of love making.”* Some implied that they might use a lubricant as well as a microbicide: *“I would imagine probably still using a lubricant gel as well. I’m not sure whether there’s any cross issues with using a [commercial lubricant] gel.”* One man wondered whether the gel might prevent the woman producing her own vaginal lubrication *“or whether she’s producing it and it’s going to come up against that [the gel] and whether then you’d have to end up using more lubricant on my part”*. Others had noted when washing that the gel became slippery and so thought it would increase lubrication during sex: *“as soon as it gets a little bit wet like when I first popped in the shower it’s just like any other lubricant, it actually works really well.”*

Some of the men were asked about use of a microbicide during oral sex and a few had concerns such as the man who said, *“I don’t know whether I’d feel comfortable with my partner smearing it on before oral sex, unless it was flavored or something like that”*. A few spontaneously mentioned the possibility of use during varied sexual activities including anal sex: *“I’ve used gels with a female partner either when things have been going pretty long and there’s a bit of a shortage in natural lubricants and on the odd occasions where there is anal, which is infrequent but it’s something to do - if there’s any toys involved, vibrators...”* and some saw this as a need for additional testing: *“I really think as well that because people’s sexuality is so diverse, ... particularly in regard to the female study there’s a lot of testing that needs to be done. As well as women there’s a whole sort of area like anal sex.”*

Although most men thought the gel would be easy to use and could see advantages when comparing it with condoms, some men appeared to regret the loss of the idea of ‘natural’ sex. For example, one man said: *“Obviously there is the normal sex like we do without any gel or anything, just arousing and both party enjoying that way”* and *“part of the fun is that whole foreplay process and basically getting each other naturally lubricated ... and “You cannot just you know just suddenly get into it where ever the fancy takes you, you are still going to have to do something prior to the act which becomes premeditated and therefore you lose the spontaneity.”*

Discussing use with partners

In general, many men felt that they were able to talk about sexual issues with their partners and did not anticipate difficulties discussing microbicides. The men were asked whether they would mind if their partner did not tell them that they were using a microbicide during sex. Several mentioned that their need to know would depend on the nature of the relationship. For example one man explained: *“I’m in a relationship at the moment so I would feel pretty unhappy about it. But if I were having a one night stand I wouldn’t know, I wouldn’t care to know, but if I found out later I don’t think it would really bother me quite so much. I’d have to think...that’s quite responsible that she’s using that gel.”* Men made frequent reference to ideals of trust and communication in long term relationships: *“It’s her choice, her body and she really can do what she likes with it, but I’d hope that the communication would be there.”* Not being open about use was viewed as a reflection on the quality of a relationship: *“It’s kind of admitting to yourself that you can’t talk about it and you don’t trust them, and maybe you should think about what you’re in.”* Several men expressed the view that it would be women’s right to decide to use a microbicide without telling their partner, such as the man who said, *“She uses heart medication before talking to me about it anyway. She does to her body what she wants to do. It’s her body and she’s entitled to look after it how she pleases.”* Some men explained that they would want to understand the reason for their partner using a microbicide: *“There has to be transparency in a relationship, there has to be honesty and you understand each others situation beforehand.”* Many of the men were unsure whether they would be able to tell if a woman was using the product. This uncertainty was related to its similarity to commercial lubricants and because they had not used the gel during sex.

Discussion

The men’s experience of the candidate microbicide was limited by the safety trial protocol to applying the gel to their penis nightly for a week, rather than using it during sex, so their views were based on anticipated use. Nevertheless, participating in the trial did prompt the men to consider aspects of microbicide use. They were generally interested in and positive about the concept of microbicides. Men tended to understand and assess microbicides for protection against STIs in relation to condoms, the only currently available method of protection against STIs. They also related microbicide gels to lubricants. These findings suggest that it will be helpful to develop product information in familiar terms. In order to encourage the uptake and acceptability of microbicides, it will be crucial to disseminate information about efficacy, safety, and descriptions of how these products work.

Most men indicated that if they were concerned about risk of infection with an STI or HIV they would only be willing to use a microbicide if it provided at least as effective protection as condoms. This is important since first generation vaginal microbicides are not expected to have high protective efficacy.²² It has been argued that microbicides might be used more widely and consistently than condoms and so have a significant impact on the spread of HIV at population level.²³ Unless a microbicide is shown to have very high efficacy our findings suggest that in Australia and other low HIV prevalence settings it is unlikely that many men

will be willing to rely on them for protection from HIV. Nevertheless, women may be keen to use microbicides if they fear that their partner will not use a condom,¹² and men who are at risk but are unwilling to use condoms might be willing to suggest a microbicide to protect against STIs. This idea is given some support by the finding that many men thought microbicide use would compare favourably with condom use. For example, a microbicide would not interrupt sex, might increase pleasure, and might be fun.

The study revealed assumptions made by men that might influence the decision to use future microbicide products and how they would use them. These include different concepts about how topical microbicides work and assumptions that they should not be used alone.

The findings that some men would only consider using a microbicide with a condom, and some were worried that people might abandon condoms in favour of microbicides, highlight the need to learn more about the ways that 'risk' and 'protection' are understood in different settings.^{24,25} Safety, pharmacokinetic, and efficacy studies need to investigate potential interactions between different prevention methods. For example, there is evidence that condoms slip off more easily when used with additional lubrication.²⁶

Most current candidate microbicides are gels and there is a range of different mechanisms of action.²⁷ Understanding the varied ways the men in this study conceptualised how a microbicide might work to prevent infection is important because their beliefs led to specific doubts about safety and efficacy which might influence future use of a microbicide. Promotional materials and anticipatory guidance should address these concerns.

While some thought that a microbicide that was also contraceptive would have the benefit of avoiding the side-effects of hormonal contraception, others raised concern about possible side-effects on both men's and women's bodies, in contrast to the perception of condoms as a contraceptive without side-effects. This is consistent with the findings of Keogh about understandings of the 'natural' body in relation to contraception.²⁸

Our study highlights important questions to explore in microbicide studies in which participants use the product during sex. While men did not use the gel during sex in the current study, they revealed very varied attitudes and beliefs about the likely lubricating properties of a microbicide, lubrication during sex in general, and women's views about lubrication. US studies of lubricants as proxy microbicides found gender differences in attitudes towards lubrication that could affect the sexual relationship and the likelihood of sustained use of microbicides.¹⁹ Clearly, it will be important to explore beliefs and practices in relation to lubrication that go beyond simple questions about preferred degree of lubrication.²⁹

Although we did not enquire specifically about use during a wide range of sexual activities, some of the men spontaneously raised questions about use of the product with repeated intercourse or during oral or anal sex. It is common to have a varied repertoire of sexual activities, especially among younger couples who may be at greater risk of STIs.^{30,31,32} Studies suggest that a significant proportion of heterosexuals have experienced anal intercourse and anal stimulation.^{33,34} Future research will need to investigate the answers to questions about the effect on safety and efficacy of the timing of application and repeat application, of ejaculate in the vagina if intercourse is repeated, and of activities such as manual genital and anal stimulation, oral sex, anal intercourse and use of sex toys. Future product information will need to provide advice in relation to these questions, although it is possible that a vaginal microbicide will be available for distribution before safety and efficacy for rectal use in humans is established. Discussion about microbicide acceptability research has tended to focus on exploring the likelihood of 'correct and consistent' use, however it is important that further research clarifies what this comprises.

Our findings suggest that men in couples discordant for viral infection may welcome microbicide use. The only options at present for herpes discordant couples are daily antiviral medication or condoms.^{35,2} Many couples fail to maintain these strategies in the long term. Future research needs to examine the attitudes of discordant couples to determine if microbicides might be seen as a more sustainable option.

Like Bentley et al we found that although many men thought it acceptable for a woman to use a microbicide without their knowledge they would prefer to be able to discuss this.¹¹ Understanding how men would like these conversations to occur might provide women with strategies to help negotiate prevention options. Fostering greater communication is important since communication is associated with increased preventive behaviors.⁶

The conclusions of this study are limited because recruitment methods and exclusion criteria required for the safety aspects of the study meant that the sample did not necessarily represent men at greatest risk of STIs. There is a need for separate acceptability studies with young men, men at high perceived risk of STIs, and those in virally discordant relationships. Nevertheless we found great interest in the concept of microbicides and a willingness to consider future use among this sample. Participants revealed a variety of beliefs and concerns that should help to inform the development of information materials and counseling guidelines, as well as important lines of enquiry for future acceptability studies, confirming the value of including an acceptability component at every stage in the phases of microbicide research.³⁶

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