Indian J Med Res 129, May 2009, pp 618-619

Correspondence

Challenges of introducing vaginal microbicides in India

Sir,

Vaginal microbicides, being designed to prevent sexual transmission of HIV and other sexually transmitted pathogens, are listed as one of the "top 10 most promising biotechnologies for improving global health"[1]. Recently presented results of the Phase II/IIB study comparing 0.5 per cent PRO 2000 and BufferGel[2] have shown 30 per cent reduction in HIV transmission, and though this decrease was not statistically significant, it is likely that a partially effective microbicide may become available in the next 5 to 7 years. However, research in this area is likely to continue for several years until a product with good efficacy becomes available.

Heterosexual transmission is the commonest route of HIV transmission in several low and middle income countries including India. Women are more vulnerable to HIV infection than men due to various biological, anatomical and social reasons[3] and majority cannot negotiate the use of a male condom, probably the only widely available effective HIV prevention technology.

A recent cost-benefit analysis conducted at the London School of Hygiene and Tropical Medicine indicated that the introduction in 73 lower-income countries of a microbicide which reduced the risk of infection by 40 per cent, at 30 per cent coverage, would avert approximately 6 million HIV infections over 3 years in men, women and children (Charlotte Watts, personal communication). Yet, its use at the individual level will depend upon risk perception of HIV, effectiveness of the product, its cost, availability and acceptability.

The new estimates of HIV in India indicate that approximately 2.5 million (2 million-3.1 million) people were living with HIV in 2006, with national adult HIV prevalence of 0.36 per cent[4]. The HIV epidemic in India, as in most parts of the world except the Sub-Saharan countries, is still primarily concentrated among populations most at risk, such as men who have sex with men, injecting drug users, sex workers and their sexual partners[4]. Thus the real challenge is to take this intervention to the 'significant' number of women who are at risk but are not aware of microbicides as an option, and ensure its consistent use. Though women who are at risk of sexually transmitted infections (STI) or HIV and cannot negotiate male condom use, will definitely benefit by using an effective microbicide, there is lack of clarity on the modalities of introducing these new products in India. Given the overall low prevalence of HIV in India, the adult population at high risk for HIV in India probably represents a very small proportion of the general population[5], therefore finding such "at-risk" population is challenging.

Vaginal products other than those for vaginal infection are rarely used in India. Women controlled vaginal contraceptive products are available in India, but are being used only by 0.6 per cent of the women[6] as few even in the health care sector know about this new technology. Use of a vaginal microbicide by women may imply that they are suspicious about the loyalty of their partner or it may reflect their own risky behaviour or HIV status. There are limited reports on acceptability of microbicides among Indian women participating in Phase I safety trials[7-9] and their acceptability perception does not represent acceptability of the product in the community.

Microbicides having contraceptive properties can be promoted at family planning clinics as contraceptives and/or as products that can prevent reproductive tract infections (RTIs) including HIV.

However, Nonoxynol-9 as a spermicide has not been very popular among women attending family planning clinics in India with only 16.9 per cent of women adopting this method for contraception and with low overall continuation rates (41.2 and 33%) at 9 and 12 months of use[10]. Sterilization remains the most widely accepted and preferred method among Indian women therefore the acceptance of a microbicide as a dual protection is likely to be limited among young women.

Vaginal cleaning may be practiced in India but cultural issues around it are not documented. Vaginal products enhancing sexual pleasure are hardly used by the majority of women therefore promoting the use of microbicides as products enhancing sexual pleasure might not help in maximizing their use. Till we do not have long acting, sustained release technology such as a silicone elastomer ring[11] or a polyurethane ring[12] for candidate microbicides, potential users will have to be informed about the consistent and correct use of the vaginal product with each act of sex. Cost of the product is an important factor affecting its sustained use and will have to be substantially low to be affordable to the majority of the population. Microbicides need to be introduced in India in a phased manner starting from at risk women and in states with high HIV prevalence. However, anything that could undermine condom use among the vulnerable population should be carefully considered. In India, the National Rural Health Mission aims to provide every village in the country with a trained woman community health activist –Accredited Social Health Activist or 'ASHA', to create awareness on health and its social determinants and it might be possible to involve her in creating awareness and advocacy for sustained use of microbicides.

To conclude, although HIV prevalence in India is much lower than previously thought, strong programmes are required to prevent the further spread of the epidemic. Microbicides when available would be an option to prevent heterosexual transmission of HIV. Introduction of microbicides in India is going to be a challenging task. In order to maximize their use, large scale awareness, targeted messages, advertising, advocacy and a national consortium are needed for the introduction of microbicides in India.

Smita Joshi[1*], Vinay Kulkarni[2]
Ramesh Paranjape[3] & Nomita Chandhiok[4]
[1*]Hirabai Cowasji Jehangir Medical Research Institute, [2]PRAYAS, [3]National AIDS Research Institute, Pune & [4]Indian Council of Medical Research New Delhi, India
[*]*For correspondence*: snjoshi@jcdc.co.in, snjnari@yahoo.com

References

1. Daar AS, Thorsteinsdottir H, Martin DK, Smith AC, Nast S, Singer PA. Top ten biotechnologies for improving health in developing countries. *Nat Genet* 2002; *32* : 229-32.
2. Trial finds microbicide promising as HIV prevention method for women. Montreal, February 9, 2009. Available at *http://www.hptn.org/web%20documents/HPTN035/MTN%20release%20%20HPTN%20035%20results.pdf*, accessed on March 2, 2009.
3. de Bruyn M. Women and AIDS in developing countries. *Soc Sci Med* 1992; *34* : 249-62.
4. AIDS Epidemic Update. December 2007. UNAIDS. Available at *http://data.unaids.org/pub/EPISlides/2007/071119_epi_pressrelease_en.pdf*, accessed on March 13, 2008.
5. Rao JV, Ganguly NK, Mehendale SM, Bollinger RC. India's response to the HIV epidemic. *Lancet* 2004; *364* : 1296-7.
6. International Institute for Population Sciences (IIPS) and Macro International. *National Family Health Survey (NFHS-3), 2005-06*: India, volume I. Mumbai: IIPS; 2007.
7. Joglekar N, Joshi S, Kakde M, Fang G, Cianciola M, Reynolds S, *et al*. HIV Prevention Trial Network 047 Protocol Team. Acceptability of PRO2000 vaginal gel among HIV un-infected women in Pune, India. *AIDS Care* 2007; *19* : 817-21.
8. Joglekar NS, Joshi SN, Navlakha SN, Katti UR, Mehendale SM. Acceptability of Praneem polyherbal vaginal tablet among HIV uninfected women & their male partners in Pune, India - Phase I study. *Indian J Med Res* 2006; *123* : 547-52.
9. Bentley ME, Fullem AM, Tolley EE, Kelly CW, Jogelkar N, Srirak N, *et al*. Acceptability of a microbicide among women and their partners in a 4-country phase I trial. *Am J Public Health* 2004; *94* : 1159-64.
10. Yadav SC, Gaur LN, Gupta N, Roy M, Saxena NC. Nonoxynol-9 vaginal pessary: a preliminary Indian experience. *Natl Med J India* 2006; *19* : 133-6.
11. Malcolm RK, Woolfson AD, Toner CF, Morrow RJ, McCullagh SD, *et al*. Long-term, controlled release of the HIV microbicide TMC120 from silicone elastomer vaginal rings. *J Antimicrob Chemother* 2005; *56* : 954-6.
12. Gupta KM, Pearce SM, Poursaid AE, Aliyar HA, Tresco PA, Mitchnik MA, *et al*. Polyurethane intravaginal ring for controlled delivery of dapivirine, a nonnucleoside reverse transcriptase inhibitor of HIV-1. *J Pharm Sci* 2008; *97* : 4228-39.