

Oral Abstract Session: Female Initiated HIV Prevention Technology

TUAC101 - Factors contributing to diaphragm size change among enrolled women at the Durban site in a phase III HIV prevention clinical trial

S.M. Govender, L.N. Mtungwa, F. Manarsingh, V. Naidoo, G. Ramjee

Medical Research Council, HIV Prevention Research Unit, Durban, South Africa

Objectives: Women are increasingly infected with HIV in Sub Saharan Africa. Recent clinical trials are now assessing the effectiveness of Microbicides and cervical barriers as HIV intervention tools. Traditionally the diaphragm, a cervical barrier, was used as a contraceptive device with a spermicide; however, is not commonly used in South Africa. MIRA (Methods of Improving Reproductive Health in Africa) is a multi site randomized controlled Phase III Clinical Trial in which the Ortho All Flex -arcing spring diaphragm and Replens gel were assessed for its effectiveness against the acquisition of HIV and STI's. Information regarding the value of diaphragm fitting is limited, and much controversy surrounds the need for diaphragm refitting.

Methods: Between November 2003 to August 2005, 1515 female participants were enrolled at Durban. All women were provided with education on diaphragm use, care and were fitted with the correct diaphragm size ranging from 55mm to 95mm. The size selected was determined and double checked by clinicians. Participants practiced insertion and removal of the diaphragm on themselves before being randomized into diaphragm/gel arm. Diaphragm checks were done at follow up visits if indicated and routinely at closing. Few diaphragm size changes were noted and contributing factors assessed.

Results: 14 out of 755 women were refit. The most common reasons were a) post-partum (vaginal/ caesarean deliveries or second trimester miscarriages) (0.7%), b) weight changes (0.13% *NB weight was not measured routinely), and c) other (1.2%), including fitting during menses and initial incorrect fitting.

Conclusions: Diaphragm fitting was reasonably consistent with few women requiring diaphragm refitting. However to ensure adequate protection is provided by the diaphragm as a contraceptive device or a possible device against STI's and HIV infection, clinicians should inquire with women about their experience with diaphragm use and evaluate any complaint that suggests a refit. Women should receive education about events that merit a refit.

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Presenting author email: *sharlenemgovender@yahoo.com*