

# Letter to the Editor

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## Establishing the safety profile of sperm washing followed by ART for the treatment of HIV discordant couples wishing to conceive

Sir,

We read with interest the ample clinical series of HIV discordant couples undergoing sperm washing and ART, reported by Savasi *et al.* (2007) in your March issue. The title and abstract of the article indicate it focuses on the safety of the sperm washing procedure which, according to the authors was investigated by serological follow-up of treated women at three and six months after each cycle. Yet, the results section only contains a general reference to the three months follow-up, and consisting in the general statement, that all tests performed were negative.

It is regrettable that the authors have chosen not to support the ambitious safety statement reported in the article abstract, of complete serological follow-up, with actual serological follow-up results. Similarly, no mention is made to the rate of the loss to follow-up or, if really none of the three and six months serologies were missing, to the system employed by the authors to ensure such complete post-treatment follow-up. It would be so remarkable that we would be delighted to know how PCR testing were made available to 100% of HIV negative women after the end of the treatment period and how obtaining perfect compliance with post-treatment follow-up was achieved.

Since its development in 1989 in Italy (Semprini *et al.*, 1992), sperm washing and IUI have been employed as a risk reduction method in HIV discordant couples wishing to conceive. *In vitro* testing following sperm washing showed that the method reduced the HIV titre in washed semen by >1000 fold (Anderson *et al.*, 1992). However, HIV heterosexual transmission is a relatively rare event, in the order of 1 to 500–1000 acts of unprotected intercourse (Gray *et al.*, 2001) and probably much lower for patients with undetectable viral load. Hence, such determination of safety requires not only a careful description of the follow-up methods and the eventual numbers lost to follow-up but needs a sufficiently large sample that has been evaluated between 3000 and 30 000 cycles (Englert *et al.*, 2004). The results section of this article should in our eyes be cautious before claiming to have reached this ambitious goal. Moreover, the authors declare that sperm washing was provided only to couples where the man was aviraemic. The risk of HIV transmission has been shown to correlate with blood viraemia levels. Gray *et al.* (2001) showed lack of HIV transmission through unprotected intercourse in couples in which the man's viral load was <1500 copies/ml. It is unclear how a

patient population in which the risk of the event of transmission is minimal can be used to indicate the safety of the intervention. In addition, the authors supply no indication or explanation of how and whether the difference in risk was foreseen and dealt with in their population and sum their results to those of other groups who reported the outcome of sperm washing in populations at different degree of transmission risk.

The evidence of low risk of HIV transmission from aviraemic men, gave way to the debate on whether these couples could be offered timed unprotected intercourse (Vernazza *et al.*, 2006). The authors of the present article affirm this option to be unacceptable. However, they seem to see no problem in abandoning couples in whom the men have unsuppressed viraemia to this forced choice. Indeed, almost two-thirds of couples who requested this procedure were excluded before treatment and positive blood viraemia was an exclusion criterion. The authors affirm that such exclusions were motivated by the desire to protect the woman. In any form of clinical treatment, choosing the patients who are most likely to have a positive outcome, while denying treatment to those in actual need, is likely to protect the medical establishment, rather than patients.

When sperm washing and ART were introduced in Italy in 1989, no exclusion criteria were posed, apart from the willingness to practice unprotected intercourse for the duration of the program. Until 1997, when highly active antiretroviral treatment (HAART) was introduced, over 1100 sperm washing and insemination cycles have been performed, with a rate of serological follow up at six months of 92.9% with no case of HIV transmission (Bujan *et al.*, 2007).

If sperm washing is to fulfil its role as a public health measure aiming to reduce the risk of HIV transmission to seronegative female partners of HIV positive men wishing to conceive, its application should be allowed and even encouraged in those couples who are actually at risk of transmission.

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