Flawed African Circumcision Trials Cannot Be Used to Inform U.S. Circumcision Debate

Mass male circumcision has been identified and promoted as a method of curbing the HIV/AIDS pandemic in sub-Saharan Africa following the results of three randomized clinical field trials (RCTs) conducted there.[1,2,3] Analysis of these studies reveals many factors that call in to question the results claimed and limit their applicability to the circumcision debate in the United States.

Questionable Results

- All three of the clinical trials conducted in sub-Saharan Africa were terminated early. More than 700 participants were lost to follow-up, their HIV status unknown; i.e., 4.5 times more participants were lost to follow-up than were reported to have been protected from HIV by circumcision. The study participants were paid, provided free condoms, and given extensive education and counseling, thus limiting the "real world" applicability of the studies.
- No consideration was given to the probability that a significant number of HIV infections were contracted through means other than sexual conduct, calling into question the entire premise of the RCTs.[4]
- All three RCTs were halted earlier than designed, including a study investigating the effect upon female infections.[5] In one study, circumcised men's infection rates were increasing toward the intact men's rate prior to the study being halted.[6] Following the study period, all participants in the "control" group were then offered circumcision, eliminating the possibility of any accurate follow-up study.
- The studies showed that male circumcision offered no protection to women.[7] Rather, circumcising men infected with HIV appeared to increase transmission of the virus to female partners.[8] Male circumcision endangers women if sex is resumed before the male's circumcision wound has completely healed,[9] and it places women at greater risk of unsafe sex practices if they or their male sexual partners believe or insist they are immune from HIV.
- Circumcision does not protect men having sex with men.[10,11]
- Circumcision is less effective, riskier, and more expensive than condom use. Researchers who modeled South African data on a computer reported that "circumcision had a limited impact in reducing both new infections (range 3%-13% reduction) and deaths (range 2%-4% reduction), and its impact was overshadowed when combined with the other interventions."[12] One analysis comparing the cost of circumcision with the cost of condoms found that condoms were 98% effective at hindering HIV transmission and reception, and 95 times more cost-effective than circumcision.[13]
- The effects of researcher bias have not been considered as part of the RCT design or results. A Cochrane Collaboration Report from 2003[14] cautioned against such bias, stating: "Circumcision practices are largely culturally determined, so there are strong beliefs and opinions surrounding them. It is important to acknowledge that researchers' personal biases and dominant circumcision practices of their respective countries may influence interpretation of findings."

Inapplicability to U.S. Context

These flawed RCTs – whose target population consisted of adult males – are now being used to influence male infant circumcision policy in the United States. Both the Centers for Disease Control and Prevention and the American Academy of Pediatrics are currently considering whether to recommend infant circumcision.

Even if the African studies were internally reliable, differences between the study population and social environment in sub-Saharan Africa and the American context render them unsuitable for drawing any conclusions about HIV prevention in the United States. First, sexual behavior and sexually transmitted diseases are notoriously difficult to study and draw reliable conclusions from. Second, HIV is transmitted through various means in addition to sexual intercourse (e.g., contaminated medical instruments and blood supply); prevention measures that focus exclusively on sexual transmission are limited. Third, the United States and sub-Saharan Africa differ in many ways, including:

- varying cultural and sexual practices, both hetero- and homosexual
- different viral strains
- different sanitary conditions
- different levels of access to preventive services and general health care

Finally, if circumcision were effective in preventing the transmission of HIV, it is highly unlikely that the United States, where most adult men are circumcised, would have higher rates of HIV prevalence than countries in Europe, where circumcision is rare. The opposite is true. No "first world" countries have embraced the suggestion of the African RCT researchers that circumcision is a reasonable prevention strategy for HIV transmission.

Ethical Considerations

Although a number of ethical questions have been raised in relation to the three RCTs concluding with a recommendation for circumcision (e.g., poor men were paid to be circumcised; both study and control populations were encouraged to be circumcised; true informed consent was unlikely, given the cultural and socioeconomic divide between the researchers and the study population), this is not the forum for debating the internal ethics of the studies. However, given that results from these studies are being used in the United States to promote adult circumcision for "high risk" (i.e., low income blacks and Hispanics) as well as routine neonatal circumcision among infant boys, it is highly appropriate to raise ethical issues in the American context. Among these:

- Circumcision permanently removes healthy, functional, and beneficial tissue.[15] It is unprecedented for a prophylactic surgery to be suggested as a "health benefit" to adults who have safer and more effective ways of avoiding infection, and to parents of newborns to reduce risks of an adult-acquired disease.[16,17] The argument that not circumcising infants denies them beneficial health care is predicated upon the assumption that circumcision's benefits outweigh its risks and harms. This has never been proven.
- Despite known complications and deaths resulting from this unnecessary surgery, the risks and harms of circumcision have never been systematically studied in the United States.
- Adult males can provide informed consent, so long as they are presented with all of the facts, including the potential risks and harms of circumcision. Newborn males cannot. Accepted bioethical principles dictate that proxy (e.g., parental) consent is limited to interventions where the child's health or life is at risk. This is not the case with infant circumcision – an elective surgical procedure that permanently removes healthy, functional tissue from a healthy baby.

Conclusion

Education, safe-sex practices, and consistent condom use are proven, effective measures of curbing HIV transmission. It is both unethical and unscientific to embrace neonatal circumcision of healthy newborn babies as a means to prevent sexually transmitted HIV years or decades in the future.

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