Safety and efficacy of nontherapeutic male circumcision: a systematic review

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CRD summary
This review assessed the safety and efficacy of non-therapeutic circumcision. It concluded that strong evidence suggested that circumcision could prevent HIV/AIDS acquisition in sub-Saharan African men. The authors’ conclusions appear reliable in reflecting the evidence presented, but it should be noted that not all relevant studies were identified for the review.

Authors' objectives
To assess the safety and efficacy of non therapeutic male circumcision.

Searching
PubMed, EMBASE, the Cochrane Library and DARE were searched for studies published between January 1997 and August 2008 (these dates were used to compliment a review performed in 1996 - see Other Publications of Related Interest). Search terms were reported.

Study selection
Randomised controlled trials (RCTs) of circumcision in an operative setting in male patients of any age with no contraindications to, or medical indications for, circumcision were eligible for inclusion. Outcomes of interest included safety, patient-reported outcomes, and the incidence of sexually transmitted infection, urinary tract infection, HIV/AIDS, and penile cancer.

Included trials were conducted in Africa and North America. African trials included adults (aged 15 years or older); the comparator groups had delayed circumcision. North American trials included neonates (mean age ranged from 27 hours to 143 days); the comparator groups received placebo analgesics or were uncircumcised.

The authors did not state how many reviewers selected studies.

Assessment of study quality
Trial quality was evaluated according to the following criteria: randomisation/allocation concealment, blinding of outcome assessors, reporting of eligibility criteria, comparability of groups at baseline, use of power calculation, length of follow-up, and losses to follow-up.

The authors did not state how many reviewers assessed study quality.

Data extraction
Data were extracted by one reviewer and checked by another, with disagreements resolved by discussion.

Methods of synthesis
A narrative synthesis was presented, but where comparable outcome data was available for at least two studies, data were pooled using a random-effects model to calculate odds ratios (ORs) with 95% confidence intervals (CIs). Heterogeneity was assessed using the I² statistic.

Results of the review
The authors reported that eight RCTs were included in the review, but there were eight published papers covering five RCTs (n=11,046 participants). Four RCTs reported using blinded outcome assessors, three reported using opaque sealed envelopes for allocation concealment, and three clearly reported using a power calculation.

Adults (three RCTs, n=10,904 participants): Circumcised sub-Saharan African men had a significantly lower risk of acquiring HIV/AIDS than uncircumcised men (OR 0.44, 95% CI 0.32 to 0.59; I²=0); all three trials were stopped early,
with numbers of events ranging from 19 to 22 in the circumcision groups and from 45 to 49 in the delayed circumcision groups. The perioperative adverse event rate across the three trials in participants receiving immediate circumcision was 4.8%; the rate of reported pain was 13.5%. No trials reported penile cancer or urinary tract infection outcomes.

**Neonates** (two RCT; n=138 neonates): One trial of circumcision, with or without paracetamol use, reported no significant differences in pain during the surgery, but the "percentage of cry" was significantly higher in the placebo group when comparing pre- and post-circumcision crying. No perioperative adverse events were reported in the two trials. No trials assessed clinical efficacy.

**Authors’ conclusions**
Strong evidence suggested that circumcision could prevent HIV/AIDS acquisition in sub-Saharan African men.

**CRD commentary**
The review addressed a clear question and was supported by appropriate inclusion criteria. Attempts to identify relevant studies were undertaken by searching relevant databases, but the authors deemed 1997 as an appropriate date to search from, since a previous review was published in 1996, so not all the relevant studies were retrieved for this review. It was unclear whether there were any language restrictions and no search was made to identify unpublished studies. Measures (independent duplicate processes) were taken to minimise the potential for error and/or bias during the data extraction process, but the authors did not report whether similar measures were applied throughout the review.

Although trial quality was assessed, the evaluations were used minimally in interpreting the results of the review. Sufficient trial details were provided. An appropriate synthesis of the data was undertaken.

The authors’ conclusions appear reliable in reflecting the evidence presented, but it should be noted that they did not seek to identify all the relevant studies.

**Implications of the review for practice and research**
**Practice:** The authors advocated the use of post-operative pain control for circumcised neonates. They also cautioned extrapolation of the HIV/AIDS prevention results to other settings where there may be a lower prevalence of HIV/AIDS and ready access to condoms.

**Research:** The authors stated that more research was needed (especially in neonates) on the role of non-therapeutic circumcision for preventing sexually transmitted infection (including HIV/AIDS), urinary tract infection, and penile cancer.

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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.