Ensuring the safety of patients during male circumcision for HIV prevention by learning from rare adverse events.

This technical brief has been developed by the World Health Organization (WHO) Technical Advisory Group on Innovations in Male Circumcision and US Centers for Disease Control and Prevention.

URETHRAL FISTULA IN VOLUNTARY MEDICAL MALE CIRCUMCISION PROGRAMMES

The WHO had received notification of 32 cases of urethral fistula following male circumcision (MC) procedures performed in voluntary medical male circumcision (VMMC) between 2014 and 2018. While such adverse events are rare, this technical brief provides information to improve practice. This brief is based on the information from those events. It addresses the potential practices that could lead to a fistula, and measures to reduce these complications through improved understanding by practitioners.

WHAT IS AN URETHRAL FISTULA?

An urethral fistula is an abnormal hole between the urinary passage (urethra) and the surface of the skin, so that the urine stream passes either partially or entirely through that hole rather than the normal urethral opening at the tip of the penis. Urethral fistulae observed in VMMC programmes presented on the underside of the penis (6 o’clock position), where the urethra is nearest to the skin and most vulnerable to damage during the MC procedure.

The diagram on page 3 shows a large urethral fistula which has persisted after failed surgery. If the fistula is large, most or all of the urine comes out through the fistula instead of the urethral meatus at the end of the penis. Sometimes, when there is a very small fistula, there may only be slight dampness and such a “pinhole” fistula can be hard to see.

SUSPECT AN URETHRAL FISTULA WHEN URINE COMES OUT THE WRONG WAY

Diagnosis of an urethral fistula is usually easy. Urine comes out through the wound between the stitches or through a hole in the frenular area on the underside of the penis, rather than the ‘normal way’ through the urethral meatus. Very often the client will be the first to notice and report leakage of urine. When the fistula is small, the client may complain of dampness. In this situation, clinic staff may not be able to see the small fistula, but they should not dismiss the client’s complaint. If staff are in doubt, they should refer the client for an expert consultation. They should NOT try to identify the fistula by probing, as this may make it worse.

HAS URETHRAL FISTULA DEVELOPMENT BEEN OBSERVED FOLLOWING ALL MALE CIRCUMCISION METHODS?

Cases of fistula have been reported after dorsal slit and forceps guided surgery. These procedures have been performed with and without use of diathermy; therefore, the complication is not isolated to a single surgical method or use of diathermy. There have been no fistula reports after male circumcision with use of a currently WHO- prequalified device method (elastic collar compression, i.e. PrePex, or collar clamp, i.e., ShangRing).
**UNDERSTANDING THE ANATOMY**

[a] The urethra is close to the surface of the skin in the frenular area. See red circle.

[b] Differences by age and physical development. The majority of reported cases of urethral fistula occurring after male circumcision for HIV prevention developed among younger clients, aged 10-14 years, probably because tissues are thinner in clients with less mature genitalia and the urethra lies closer to the skin.

[c] All providers need to keep the anatomy, and client's physical development, in mind when performing any surgical procedure that involves the frenular area. This includes identifying the frenular area, and taking care when cutting away the foreskin, stopping bleeding and placing the frenular horizontal mattress suture.

**TIMING AND CAUSES OF URETHRAL FISTULA**

When a fistula may first become apparent

The appearance of a fistula tends to occur during one of two time frames.

[a] Early cases (within 36 hours):
Urine comes out through the suture line or through a hole other than the urethral meatus. This is likely to be caused by a deep cut into the urethra or a deep stitch into and blocking the urethra.

[b] Later cases (36 hrs - several weeks):
When urine begins passing through a hole other than the urethra days or weeks after surgery, then the likely cause is damage to the tissues in the wall of the urinary passage and tissue necrosis which take several days or weeks to become a hole. Thus, post-operative progress appears normal for the few days.

Causes of fistula

Direct cut into the urethra at the time of surgery. This damage may occur if the plane of cutting is taken too close to the base of the frenulum. This may occur due to time pressure and an overhurried provider. See the figure (page 3) on how to angle the scissors away from the danger area and avoid cutting near the base of the frenulum.

Stitches that are placed too deeply and which pierce or include part of the urethra. Misplaced sutures, particularly if tied too tightly, can cause a fistula by stopping the blood supply to a chunk of tissue, thus causing tissue necrosis which then breaks down to form a hole. A deep stitch may also block the urethra resulting in inability to pass urine and urine coming out through the suture line. Misplacement may occur when sutures are used to stop bleeding from the frenular artery or when placing the 6 o’clock horizontal mattress suture during closure of the circumcision wound. Sutures should not be placed deeper than the red dotted line in the figure.

Deep diathermy burns. Prolonged diathermy can cause a deep burn involving part or all of the urethral wall. Diathermy burns extending into the urethral wall cause tissue necrosis.
When undertaking dorsal slit circumcision (see Resources: Manual chapter 9 Fig 9.25b) take particular care in the final stages of cutting away the foreskin when cutting in the frenular area (6 o’clock position). The path of the scissors or knife should follow a V-shape that has been previously marked so that the cut does not shave close to the base of the frenulum. If the cut in the frenular area is taken close to the base of the frenulum, then bleeding from the frenular artery may be more difficult to control. There is also a risk that the cut will be too deep and into the urethra.

Take particular care when stopping bleeding in the region of the frenular area. If it is necessary to place a suture to stop bleeding, remain calm and don’t panic! Take time to accurately locate the bleeding vessel and take care not to catch deeper layers of tissue in the suture. Grasping the tissue to suture, then gently tenting it up and away from deeper tissues, may help proper stitch placement.

While diathermy has not been implicated in every fistula occurrence, it is plausible that indiscriminate use in the frenular area could lead to necrosis of the tissue separating the frenulum from the urethra, particularly among younger clients in whom this tissue is very thin. Hence, diathermy should not be used to control bleeding in the frenular area.

Any damage extending deeper than the red dotted line in the figure may allow wound infection into deeper layers and into the urethral wall which makes a fistula more likely to occur.

As with any type of adverse event, the risk for fistula may be increased when providers are inexperienced, rushed, or overtired.
**WHAT TO DO IF YOUR CLIENT DEVELOPS FISTULA**

[a] Unfortunately, once a fistula develops it is often difficult to treat; therefore all such cases should be referred to a specialist surgeon with expertise in urethral surgery and fistula repair. This is important because the best chance of a good result is after the first repair operation. If the first repair operation fails, then it becomes increasingly difficult to repair (Note the diagram on page 3 that shows a fistula after several failed repair operations).

[b] Do not attempt to do the repair operation in the circumcision clinic, as repair operations done by non-specialists nearly always fail and result in continuing and sometimes lifelong complications, including persistent fistula, bent erections and social and psychological damage.

[c] Do not attempt catheterisation in the circumcision clinic unless advised to do so after consultation with the specialist surgeon. Provided that urine is coming out through the fistula there is no urgency to pass a catheter. There is time for consultation with the specialist surgeon and for the client to travel to the specialist hospital. If a catheter is necessary because the man cannot pass urine, then he should be sent to the nearest hospital. In very exceptional circumstances, it may be necessary to pass a catheter in the circumcision clinic; if so, this should be done in the procedure room, with good lighting and by the most experienced provider in the clinic team.

[d] Carefully review the case record and make a full report. (Note the purpose of making a detailed report is so that we can better understand why problems occur and then we can try to improve instruction. This brief is based on the information we have at present but we need better information). The report should include:

- the experience of the person who did the circumcision (duration of service as a VMMC provider, approximate number of VMMCs ever conducted prior to the case)
- date of procedure
- the method of circumcision used
- whether diathermy was used
- the suture material and needle size used
- date the client first noticed urine coming out the wrong way
- note of any complications such as difficult frenular bleeding or infection
- whether antibiotics were given

WHO is providing a reporting form that can be used for this purpose. Please complete and share with your WHO Country Office.

[e] Seek permission of the client or client and guardians to take photographs. These are very helpful in characterising the nature of the fistulae.

[f] Refer the client for further care to a specialist with expertise in urethral surgery and fistula repair, this will often be a urologist. The national programme should give you the name of the specialist surgeon to contact. Referral protocols should be made in advance for each clinic, so that there are no administrative difficulties or delays when a fistula occurs.

[g] Make sure that the client and his family are fully informed about what has happened and what treatment is planned and give psychosocial support to the client and the family during the period of care until final discharge.

**WHAT THE CLINIC SHOULD DO TO PREPARE FOR RARE ADVERSE EVENTS SUCH AS URETHRAL FISTULA?**

As an urethral fistula is a rare adverse event, it may never be seen in a particular clinic. Ideally, each clinic where male circumcisions are performed should have regular briefing sessions with clinic staff to discuss adverse events and also this and any other special briefing notices. A management plan should be discussed and each clinic should identify in advance the appropriate referral pathway to have in place.

**Resource:**

*Manual for male circumcision under local anaesthesia and HIV prevention services for adolescent boys and men*, WHO and Jhpiego, 2018. See Chapter 8 for correct surgical and diathermy technique; Chapter 9 for step by step guide to correct surgical procedure.