

## CLINICAL MANAGEMENT OF FEMALE GENITAL MUTILATION MUST BE HANDLED WITH UNDERSTANDING, COMPASSION

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### In Brief • En bref

Canadian obstetricians, gynecologists and family practitioners are not allowed to perform female genital mutilation (FGM), but because of immigration patterns it is still a reality for them. Dr. André Lalonde, an Ottawa obstetrician-gynecologist who serves as executive vice-president of the Society of Obstetricians and Gynaecologists of Canada, offers some practical suggestions from his own experience for physicians unaccustomed to seeing patients who have experienced FGM.

Les obstétriciens, les gynécologues et les médecins de famille du Canada n'ont pas le droit de pratiquer de mutilations génitales chez les femmes, mais à cause des tendances de l'immigration, le problème demeure une réalité pour eux. Le Dr André Lalonde, obstétricien-gynécologue d'Ottawa, qui est aussi vice-président exécutif de la Société des obstétriciens et gynécologues du Canada, présente quelques suggestions pratiques tirées de son expérience personnelle aux médecins qui ne sont pas habitués à accueillir des patientes qui ont subi des mutilations génitales.

Canada's physicians are not allowed to perform female genital mutilation (FGM), but because of immigration patterns it is still a reality for the country's obstetricians, gynecologists and family practitioners. The practice is common in 26 African countries as well as the Middle East, Indonesia, Malaysia, India and Pakistan, and with increased immigration to Canada, particularly from north African countries, more women who visit gynecologists' offices have undergone clitoridectomy and/or closure of the vagina. Data from the Canadian Advisory Council on the Status of Women indicate that between 1986 and 1991 nearly 40 000 women who arrived in Canada from northern and

eastern Africa had experienced some form of FGM.

Such patients are usually referred to a gynecologist because the woman, now an adult, wishes to marry, have intercourse and/or begin a family. I have managed the care of a number of patients who became pregnant even though the vagina was closed save for a small opening of a half-centimetre or less at the posterior fourchette of the vagina.

The repair can be done effectively and easily through outpatient surgery that is performed under general anesthesia. The surgeon introduces an obstetrical dilator into the narrow opening at the posterior fourchette to elevate the skin and then, with sharp scissors, makes an incision up to the clitoral hood or the periurethral area. This effects an

immediate opening of the vagina. The vulva is then repaired using fine absorbable sutures in an interrupted manner. There is very little blood loss.

Inspection of the hymenal area is undertaken. In the 10 cases I have managed, we have never seen a complete closure of the hymen once the vulva-vaginal skin coverage has been opened. Usually the clitoris is absent. In two cases, however, the clitoris was present underneath this skin closure.

Fine absorbable sutures are indicated for lessening scarring around the vulva. This procedure can be done on an outpatient basis and the patient has to be advised not to have intercourse for 2 to 3 weeks, after which healing should be complete.

This may seem like obvious advice, but several of my patients felt that they could begin or resume intercourse immediately after the surgery. This procedure obviously cannot be done the day before a wedding; when possible, patients should be made aware of this. Careful counselling of the man who accompanies the patient is extremely important in these cases.

If a pregnant patient presents but vaginal penetration has not occurred, it may be best to wait until the patient is in labour and fully dilated before acting. The physician then uses a metal catheter and makes an incision to release the opening of

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the vagina. Following the delivery, physicians can proceed with the repair as described above. I have dealt with two of these patients in the last 2 years with no difficulty and no need of extensive episiotomy.

Language is often a barrier to communication with these patients, but my impression is that they do not appear to be overly stressed by their experience; this may not be the case for girls. It is very difficult to establish whether this procedure has caused any permanent psychosexual damage. My patients have not wanted to discuss the very difficult experience of FGM, but indicated that they wanted to get on with their lives.

Most of my patients seemed to want to adapt to Western culture, however, and have never indicated

to me or my nursing assistants any desire to have the vagina reclosed. At no time have I been requested, either by a patient or her husband, to repeat the procedure.

When it passed a policy statement in September 1992 that condemned the practice of female genital mutilation, the Society of Obstetricians and Gynaecologists of Canada (SOGC) said women who have been subjected to such procedures should be treated with understanding and compassion. Clinical management is only part of the physician's challenge; health promotion and counselling is also important, but doctors must be sensitive to the patient's culture, customs and tradition. We may condemn the practice of FGM, but we must never condemn the women

who as children were its innocent victims.

[The practice of female genital mutilation has been widely condemned by the World Medical Association, as well as Canadian medical organizations such as the SOGC, the CMA, the Federation of Medical Women of Canada, and the colleges of physicians and surgeons of British Columbia, Alberta and Ontario. Dr. May Cohen, chair of the CMAs Gender Issues Committee, says that in addition to condemning the practice of FGM, the medical profession has an important role to play in teaching physicians how to give supportive, culturally sensitive and understanding care to patients who present with FGM-related conditions and needs. — Ed.] ■

#### AXID® Lilly - Nizatidine Histamine H<sub>2</sub> Receptor Antagonist

**Action:** Nizatidine is a competitive, reversible inhibitor of the histamine H<sub>2</sub> receptor of gastric-acid secreting cells. Nizatidine is not an anticholinergic agent. It inhibits nocturnal gastric-acid secretion as well as gastric-acid secretion stimulated by food, caffeine, betazole and pentagastrin. Pepsin output is reduced in proportion to the reduced volume of gastric secretions. Nizatidine has little or no effect on basal serum gastrin or food induced hypergastrinemia. In man nizatidine is absorbed rapidly, peak plasma concentrations occur from 0.5 to 3 hours after an oral dose. Approximately 90% of an oral dose of nizatidine is excreted in the urine within 12 hours, with about 60% as unchanged drug. The elimination half-life is one to two hours and the systemic plasma clearance is about 50 L/hour. Antacids consisting of aluminum and magnesium hydroxides with simethicone decrease absorption of nizatidine by about 10%. With food the AUC and C<sub>max</sub> increase by approximately 10%. Renal impairment significantly prolongs the half-life and decreases the clearance of nizatidine.

**Indications and Usage:** AXID (nizatidine) is indicated in the treatment of conditions where a controlled reduction of gastric acid secretion is required such as, for ulcer healing and/or pain relief: acute duodenal ulcer, acute benign gastric ulcer, gastroesophageal reflux disease, and prophylactic use in duodenal ulcer.

**Contraindications:** AXID (nizatidine) is contraindicated for patients with known hypersensitivity to the drug. Because cross sensitivity in this class of compounds has been observed, H<sub>2</sub>-receptor antagonists, including AXID, should not be administered to individuals with a history of previous hypersensitivity to other agents.

**Precautions:** *Use in Gastric Ulcer:* Where gastric ulcer is suspected the possibility of malignancy should be excluded before therapy with AXID (nizatidine) is instituted. *Use in Pregnancy and Lactation:* The safety of AXID during pregnancy has not been established. Reproduction studies performed in rats and rabbits at doses up to 300 times the human dose have revealed no evidence of impaired fertility or teratogenicity. If the administration of AXID is considered to be necessary, its use requires that the potential benefits be weighed against possible hazards to the patient and to the fetus. Nizatidine is secreted in human breast milk in proportion to maternal plasma concentrations (<0.1%), and caution should be exercised when AXID is administered to nursing mothers. *Use in Impaired Renal Function:* As nizatidine is excreted via the kidney, dosage should be adjusted in patients with moderately or severely impaired renal function (see Dosage and Administration). *Use in Hepatic Dysfunction:* Nizatidine is partially metabolized in the liver; however, in patients with mild to moderate hepatic dysfunction, disposition of nizatidine is similar to that of normal subjects. *Use in Elderly Patients:* Ulcer healing rates in elderly patients are similar to those in younger age groups. The incidence rates of adverse events and laboratory test abnormalities are also similar to those seen in other age groups. Age alone is not an important factor in determining the disposition of nizatidine. However, elderly patients may have reduced renal function (see Dosage and Administration). *Pediatric Use:* The safety and effectiveness of nizatidine in children has not been established. *Laboratory Tests:* False-positive tests for urobilinogen with Multistix® may occur during therapy with nizatidine. *Drug Interactions:* No interactions have been observed between AXID and theophylline, chloridiazepoxide, lorazepam, lidocaine, phenytoin, warfarin, aminophylline, diazepam, and metoprolol. AXID does not inhibit the cytochrome P-450-linked drug-metabolizing enzyme system; therefore, drug interactions mediated by inhibition of hepatic metabolism are not expected to occur. In patients given very high doses (3,900 mg) of ASA daily, increases in serum salicylate levels were seen when nizatidine, 150 mg b.i.d., was administered concurrently.

**Adverse Reactions:** Clinical trials of nizatidine included almost 5,000 patients given nizatidine in studies of varying durations. North American placebo-controlled trials included over 1,900 patients given nizatidine and over 1,300 given placebo. Among the more common adverse events in these placebo-controlled trials, sweating (1% vs. 0.2%), urticaria (0.5% vs. less than 0.01%), and somnolence (2.4% vs. 1.3%) were significantly more common in the nizatidine group. A variety of less common events were also reported; it was not possible to determine whether these were caused by nizatidine. *Hepatic:* Hepatocellular injury, evidenced by elevated liver enzyme tests (SGOT[AST], SGPT[ALT], or alkaline phosphatase), occurred in some patients possibly or probably related to nizatidine. In some cases there was marked elevation of SGOT, SGPT enzymes (greater than 500 IU/L) and in a single instance SGPT was greater than 2,000 IU/L. The overall rate of occurrences of elevated liver enzymes and elevations to 3 times the upper limit of

normal, however, did not significantly differ from the rate of liver enzyme abnormalities in placebo treated patients. Hepatitis and jaundice have been reported. All abnormalities were reversible after discontinuation of AXID. **Cardiovascular:** In clinical pharmacology studies, short episodes of asymptomatic ventricular tachycardia occurred in 2 individuals administered nizatidine and in 3 untreated subjects. **Central Nervous System:** Rare cases of reversible mental confusion have been reported. **Endocrine:** Clinical pharmacology studies and controlled clinical trials showed no evidence of antiandrogenic activity due to AXID. Impotence and decreased libido were reported with equal frequency by patients who received AXID and by those given placebo. Rare reports of gynecomastia occurred. **Hematologic:** Fatal thrombocytopenia was reported in a patient who was treated with AXID and another H<sub>2</sub>-receptor antagonist. On previous occasions, this patient had experienced thrombocytopenia while taking other drugs. Rare cases of thrombocytopenic purpura have been reported. **Integumental:** Sweating and urticaria were reported significantly more frequently in nizatidine than in placebo patients. Rash and exfoliative dermatitis were also reported. **Hypersensitivity:** As with other H<sub>2</sub>-receptor antagonists, rare cases of anaphylaxis following administration of nizatidine have been reported. Because cross sensitivity in this class of compounds has been observed, H<sub>2</sub>-receptor antagonists should not be administered to individuals with a history of previous hypersensitivity to these agents. Rare episodes of hypersensitivity reactions (eg. bronchospasm, laryngeal edema, rash and eosinophilia) have been reported. **Other:** Hyperuricemia unassociated with gout or nephrolithiasis was reported. Eosinophilia, fever and nausea related to nizatidine administration have been reported.

**Symptoms and Treatment of Overdosage:** There is little clinical experience with deliberate overdosage of AXID (nizatidine) in humans. Test animals that received large doses of nizatidine have exhibited cholinergic-type effects, including lacrimation, salivation, emesis, miosis, and diarrhea. Should overdosage occur, use of activated charcoal, emesis, or lavage should be considered along with clinical monitoring and supportive therapy. Renal dialysis does not substantially increase clearance of nizatidine due to its large volume of distribution.

**Dosage and Administration:** *Duodenal or Gastric Ulcer:* One 300 mg capsule or two 150 mg capsules once daily at bedtime. Alternatively 150 mg twice daily may be used. Healing occurs within 4 weeks in most cases of duodenal ulcer; but if healing is not documented or has not occurred, therapy should be given for 8 weeks. *Maintenance Therapy in Duodenal Ulcer:* One 150 mg capsule once daily at bedtime for 6 to 12 months depending on the severity of the condition. *Gastroesophageal Reflux Disease:* One 150 mg capsule twice daily for the treatment of erosions, ulcerations, and associated heartburn. Antacids may be given concomitantly if needed.

**How Supplied:** AXID (nizatidine) Pulvules 3144 150 mg, pale yellow and dark yellow. Bottles of 100. AXID (nizatidine) Pulvules 3145 300 mg, pale yellow and brown. Bottles of 100. AXID is a Schedule F drug and cannot be obtained without a written order from a licenced practitioner.

#### Drug Adjustment in Renal Impairment:

| Renal Function      | Creatinine Clearance (mL/min) | Dosage         |                |
|---------------------|-------------------------------|----------------|----------------|
|                     |                               | Acute          | Maintenance    |
| Normal              | >50                           | 300 mg/day     | 150 mg/day     |
| Moderate Impairment | 20-50                         | 150 mg/day     | 150 mg/2nd day |
| Severe Impairment   | <20                           | 150 mg/2nd day | 150 mg/3rd day |

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Product monograph available on request.

References: 1. Axid Product Monograph. 2. Ranitidine Product Monograph. 3. Cimetidine Product Monograph. 4. Famotidine Product Monograph. 5. Heartburn Survey. Data on file. Lilly Research Laboratories, 1991. 6. Cloud M, Offen W. *Digestive Diseases and Sciences* 1992; 37(6): 865-874. 7. Cloud M, Offen W, Amer J. *Gastroenterol* 1991; 86(12): 1735-1742.

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