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Controversy Rages Over Female Genital Cosmetic Surgery

4 We're all struggling in our practices, but ... if our duty is to provide ethical care, in my opinion we can't do cosmetic cash procedures.

BY BETSY BATES

bstetrics and gynecology, under siege by diminishing reimbursement and escalating malpractice premiums, has broadly expanded its scope over recent years to include not only primary care but now, the cosmetic treatment of wrinkles, age spots, and love handles.

The trend has met with mild consternation voiced at medical meetings and in the commentary sections of professional journals, but little fervent pushbackwith one notable exception: commercialization of cosmetic genital surgery.

Cosmetic labial surgery and vulvar fat transfers have been at the center of escalating controversy in the literature, pitting critics against proponents in a battle of words over medical ethics, evidence-based medicine, and philosophical questions of free choice and societal pressure.

An opinion about "procedures that are not medically indicated" issued in 2007 by the American College of Obstetricians and Gynecologists' Committee on Gynecology Practice was considered too tepid by some critics in its recommendation that women be educated about the lack of evidence supporting the efficacy and safety of cosmetic vulvovaginal surgery.

Doing such procedures and advertising them with photographs of purportedly "attractive" versus "unattractive" genitalia constitute a violation of the ethical relationship gynecologists have with their patients, maintains Dr. Paul Indman, an ob.gyn. in solo private practice in Los Gatos, Calif.

What we do is destroy women's selfesteem [with such photographs] and then charge them a lot of money to fix what we have destroyed. I think our job as gynecologists is to help women understand what the range of normal is, [to counteract] society-caused, societyinfluenced perceived differences," he said in an interview.

See Cosmetic Surgery page 10

California Focuses On Reducing Maternal Mortality

BY MARY ELLEN SCHNEIDER

In California, reducing maternal mortal-ity has become a major public health goal.

That's in part because the state has 550,000 births per year, or about 1 in 8 of the births in the United States. The other factor driving action is that state mortality data seem to indicate a rise in maternal mortality in recent years.

"I think we've all been lulled to sleep by how we have done over the last 40 years,' said Dr. Elliott Main, chief of obstetrics at Sutter Health's California Pacific Medical Center in San Francisco and the principal investigator for the California Maternal Quality Care Collaborative. "It's sort of unbelievable that [maternal mortality] could go up, but I think there's real evidence that it is creeping up again.'

Dr. Main headed up the team that recently analyzed California's maternal mortality data. Although his official report is still being reviewed by the California See Maternal Mortality page 3



"I think there's real evidence that [maternal mortality] is creeping up again," Dr. Elliott Main said.

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An Unmet Need or Exploitation?

Cosmetic Surgery from page 1

Dr. Robert D. Moore represents another point of view.

He and longtime partner Dr. John R. Miklos began incorporating cosmetic gynecologic procedures in their practice at the Atlanta Center for Laparoscopic Urogynecology and Reconstructive Pelvic Surgery 10 years ago to fill an unmet need, he said in an interview. "We were starting to see some of

these procedures being done, and to be

TOVIAZ® (fesoterodine fumarate) extended release tablets

BRIEF SUMMARY OF PRESCRIBING INFORMATION. The following is a brief summary only; see full Prescribing Information for complete product inform

Toviaz is indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency.

glaucoma. Toviaz is also contraindicated in patients with urinary retention, gastric retention, or uncontrolled narrow-angle

Bladder Outlet Obstruction: Toviaz should be administered with caution to patients with clinically significant bladder outlet obstruction because of the risk of urinary retention (see CONTRAINDICATIONS).

Decreased Gastrointestinal Motility: Toviaz, like other antimuscarinic drugs, should be used with caution in patients with decreased gastrointestinal motility, such as those with severe constipation.

Reduced Hepatic Function: There are no dosing adjustments for patients with mild or moderate hepatic

impairment. Toviaz has not been studied in patients with severe hepatic impairment and therefore is not recommended for use in this patient population (see CLINICAL PHARMACOLOGY, Pharmacokinetics in Special Populations in full prescribing information and DOSAGE AND ADMINISTRATION).

Myasthenia Gravis: Toviaz should be used with caution in patients with myasthenia gravis, a disease characterized by decreased cholinergic activity at the neuromuscular junction.

Reduced Renal Function: There are no dosing adjustments for patients with mild or moderate renal insufficiency. Doses of Toviaz greater than 4 mg are not recommended in patients with severe renal insufficiency (see CLINICAL PHARMACOLOGY, Pharmacokinetics in Special Populations in full prescribing information and DOSAGE AND ADMINISTRATION).

Concomitant Administration with CYP3A4 Inhibitors: Doses of Toviaz greater than 4 mg are not recommended in patients taking a potent CYP3A4 inhibitor (e.g. ketoconazole, itraconazole, clarithromycin).

In patients taking weak or moderate CYP3A4 inhibitors (e.g. erythromycin), careful assessment of tolerability at the 4 mg daily dose is advised prior to increasing the daily dose to 8 mg. While this specific interaction potential was not examined by clinical study, some pharmacokinetic interaction is expected, albeit less than that observed with potent CYP3A4 inhibitors (see CLINICAL PHARMACOLOGY, Drug-Drug Interactions in full prescribing information and DOSAGE AND ADMINISTRATION).

Information for Patients Patients should be informed that Toviaz, like other antimuscarinic agents, may produce clinically significant adverse effects related to antimuscarinic pharmacological activity including constipation and urinary retention. Toviaz, like other antimuscarinics, may be associated with blurred vision, therefore, patients should be advised to exercise caution until the drug's effects on the patient have been determined. Heat prostration (due to decreased sweating) can occur when Toviaz, like other antimuscarinic drugs, is used in a hot environment. Patients should also be informed that alcohol may enhance the drowsiness caused by Toviaz, like other anticholinergic agents. Patients should read the patient leaflet entitled "Patient Information TOVIAZ" before starting therapy with Toviaz.

Drug Interactions Coadministration of Toviaz with other antimuscarinic agents that produce dry mouth, constipation, urinary retention, and other anticholinergic pharmacological effects may increase the frequency and/or severity of such effects. Anticholinergic agents may potentially alter the absorption of some concomitantly administered drugs due to anticholinergic effects on gastrointestinal motility. Also see **PRECAUTIONS, Concomitant Administration with CYP3A4 Inhibitors**.

Controlled Narrow-Angle Glaucoma: Toviaz should be used with caution in patients being treated for nar angle glaucoma, and only where the potential benefits outweigh the risks (see CONTRAINDICATIONS).

R only

INDICATIONS AND USAGE

CONTRAINDICATIONS

PRECAUTIONS

honest, the results were not very good at all. Clearly the surgeons who were doing it did not have experience or expertise in doing reconstructive surgery in this region, and patients were being harmed. "In my mind, it's a natural field for specialists like ourselves to be involved in," particularly after undergoing specialized training, he said. Whether women need the surgery is

not a question Dr. Moore considers

or narrow

relevant, although he and the other surgeons interviewed for this article all said they refuse to operate on women being pressured by a partner or those who have signs of psychiatric diagnoses such as body dysmorphic disorder.

"Normal is in the eye of the beholder," said Dr. Moore.

To question whether patients know enough about normal genital variations to make an informed decision "is an insult to women's intelligence and confidence," he said.

Spearheaded by a small handful of well-known, maverick gynecologic surgeons, including some, like Dr. Miklos and Dr. Moore, who pioneered minimally invasive surgical methods considered standard of care today, the controversial procedures often address purely aesthetic desires of consumers, rather than traditional medical indications.

In some cases, clinicians offering the procedures also cite functional indications, such as diminished sexual satisfaction or entrapment of hypertrophic labia with intercourse.

A review of 131 cases published by Dr. Miklos and Dr. Moore found that 37% of women undergoing labiaplasty cited purely aesthetic concerns (including their appearance in tight clothing), 32% cited functional impairment (such as discomfort while bicycling), and 31% had both concerns (J. Sex. Med. 2008:5:1492-5).

In his Los Angeles practice, though, only the "rare" woman cites functional discomfort, said Dr. David Matlock, who



'This is something that is a service to enhance patients' self-concepts.'

DR. PELOSI

directs the Laser Vaginal Rejuvenation Institute of Los Angeles and has trademarked terms such as Laser Vaginal Rejuvenation, Designer Laser Vaginoplasty, and the G-Shot, or G-Spot Amplification.

In most cases, "it's aesthetic surgery. It's personal preference," driven in part by social trends, including Brazilian waxing. (A Brazilian wax removes the hair around the panty line, leaving only a broad vertical strip of hair.)

"You don't need your breasts done, tummy tucked, or nose done. None of it is indicated. The patient wants to alter something. I listen to what the patient wants," he said in an interview.

As opposed to surgical innovations that enter the literature through clinical trials, results of which are presented at scientific meetings, "designer vaginoplasty" and aesthetic procedures are taught at profitable seminars such as those advertised in this publication and sponsored by surgeons such as Dr. Marco A. Pelosi II, director of the Pelosi Medical Center in Bayonne, N.J., and cofounder with his son, Dr. Marco A. Pelosi III, of the newly established International Society of Cosmetogynecology.

The elder Dr. Pelosi staunchly defended the profit motive for offering cosmetic gynecology training, saying that the objective is "totally different" from relatively inexpensive training obtained through professional medical societies. He and a small group of experts spent years developing these procedures and quite reasonably should be compensated for sharing their specialized knowledge with surgeons who stand to profit from what they learn, he said.

Continued on following page

Geriatric Use

Geriatric Use Of 1567 patients who received Toviaz 4 mg/day or 8 mg/day in the Phase 2 and 3, placebo-controlled, efficacy and safety studies, 515 (33%) were 65 years of age or older, and 140 (9%) were 75 years of age or older. No overall differences in safety or effectiveness were observed between patients younger than 65 years of age and those 65 years of age or older in these studies; however, the incidence of antimuscarinic adverse events, including dry mouth, constipation, dyspepsia, increase in residual urine, dizziness (at 8 mg only) and urinary tract infection, was higher in patients 75 years of age and loder as compared to younger patients (see CLINICAL PHARMACOLOGY, Pharmacokinetics in Special Populations and CLINICAL STUDIES in full prescribing information and ADVERSE REACTIONS).

ADVERSE REACTIONS The safety of Toviaz was evaluated in Phase 2 and 3 controlled trials in a total of 2859 patients with overactive bladder of which 2288 were treated with fesoterodine. Of this total, 782 received Toviaz 4 mg/day, and 785 received Toviaz 8 mg/day in Phase 2 or 3 studies with treatment periods of 8 or 12 weeks. Approximately 80% of these patients had >10 weeks exposure to Toviaz in these trials.

A total of 1964 patients participated in two 12-week, Phase 3 efficacy and safety studies and subsequent open-label extension studies. In these 2 studies combined, 554 patients received Toviaz 4 mg/day and 566 patients received Toviaz 8 mg/day.

In Phase 2 and 3 placebo-controlled trials combined, the incidences of serious adverse events in patients receiving placebo, Toviaz 4 mg, and Toviaz 8 mg were 1.9%, 3.5%, and 2.9%, respectively. All serious adverse events were judged to be not related or unlikely to be related to study medication by the investigator, except for four patients receiving Toviaz who reported one serious adverse event each: angina, chest pain, gastroenteritis, and QT prolongation on ECG.

The most commonly reported adverse event in patients treated with Toviaz was dry mouth. The incidence of dry mouth was higher in those taking 8 mg/day (35%) and in those taking 4 mg/day (19%), as compared to placebo (7%). Dry mouth led to discontinuation in 0.4%, 0.4%, and 0.8% of patients receiving placebo, Toviaz 4 mg, and Toviaz 8 mg, respectively. For those patients who reported dry mouth, most had their first occurrence of the event within the first month of treatment.

The second most commonly reported adverse event was constipation. The incidence of constipation was 2% in those taking placebo, 4% in those taking 4 mg/day, and 6% in those taking 8 mg.

Table 3 lists adverse events, regardless of causality, that were reported in the combined Phase 3, randomized placebo-controlled trials at an incidence greater than placebo and in 1% or more of patients treated with Tovia. 4 mg or 8 mg once daily for up to 12 weeks.

Table 3. Adverse events with an incidence exceeding the placebo rate and reported by ${\geq}1\%$ of patients from double-blind, placebo-controlled Phase 3 trials of 12 weeks' treatment duration

System organ class	Preferred term	Placebo N=554 %	Toviaz 4 mg/ day N=554 %	Toviaz 8 mg/ day N=566 %
Gastrointestinal disorders	Dry mouth	7.0	18.8	34.6
	Constipation	2.0	4.2	6.0
	Dyspepsia	0.5	1.6	2.3
	Nausea	1.3	0.7	1.9
	Abdominal pain upper	0.5	1.1	0.5
Infections	Urinary tract infection	3.1	3.2	4.2
	Upper respiratory tract infection	2.2	2.5	1.8
Eye disorders	Dry eyes	0	1.4	3.7
Renal and urinary disorders	Dysuria	0.7	1.3	1.6
	Urinary retention	0.2	1.1	1.4
Respiratory disorders	Cough	0.5	1.6	0.9
	Dry throat	0.4	0.9	2.3
General disorders	Edema peripheral	0.7	0.7	1.2
Musculoskeletal disorders	Back pain	0.4	2.0	0.9
Psychiatric disorders	Insomnia	0.5	1.3	0.4
Investigations	ALT increased	0.9	0.5	1.2
	GGT increased	0.4	0.4	1.2
Skin disorders	Rash	0.5	0.7	1.1

ALT=alanine aminotransferase, GGT=gamma glutamyltransferase

ALT-adatinite antiniortansierase, GGT =gamma guitarity/transierase Patients also received Toviaz for up to three years in open-label extension phases of one Phase 2 and two Phase 3 controlled trials. In all open-label trials combined, 857, 701, 529, and 105 patients received Toviaz for at least 6 months, 1 year, 2 years, and 3 years respectively. The adverse events observed during long-term, open-label studies were similar to those observed in the 12-week, placebo-controlled studies, and included dry mouth, constipation, dry eyes, dyspepsia and abdominal pain. Similar to the controlled studies, most adverse events of dry mouth and constipation were mild to moderate in intensity. Serious adverse events, judged to bat least possibly related to study medication by the investigator, and reported more than once during the open-label treatment period of up to 3 years included urinary retention (3 cases), diverticu-litis (3 cases), constipation (2 cases), irritable bowel syndrome (2 cases), and electrocardiogram QT cor-rected interval prolongation (2 cases).

OVERDOSAGE

Overdosage with Toviaz can result in severe anticholinergic effects. Treatment should be symptomatic and supportive. In the event of overdosage, ECG monitoring is recommended. DOSAGE AND ADMINISTRATION

The recommended starting dose of Toviaz is 4 mg once daily. Based upon individual response and tolerability, the dose may be increased to 8 mg once daily.

The daily dose of Toviaz should <u>not</u> exceed 4 mg in the following populations: • Patients with severe renal insufficiency (CL_{cR} <30 mL/min). • Patients taking potent CYP3A4 inhibitors, such as ketoconazole, itraconazole, and clarithromycin.

Toviaz is not recommended for use in patients with severe hepatic impairment (see CLINICAL PHARMACOL-OGY, Pharmacokinetics in Special Populations in full prescribing information and PRECAUTIONS). Toviaz should be taken with liquid and swallowed whole. Toviaz can be administered with or without food, and should not be chewed, divided, or crushed.

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LAB-0381-3.0

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Fesoterodine was not mutagenic or genotoxic in vitro (Ames tests, chromosome aberration tests) or in vivo nouse micronucleus test).

Drug Interactions

Drug-Laboratory Test Interactions

Pregnancy Category C Reproduction studies have been performed in mice and rabbits. No dose-related teratogenicity was observed at oral doses up to 75 mg/kg/day in mice (6 to 27 times the expected exposure at the MRHD based on AUC and greater than 77 times the expected C_{mw}) and up to 27 mg/kg/day in rabbits (3- to 11-fold by AUC and 19- to 62-fold by C_{mw}) or at subcutaneous doses up to 4.5 mg/kg/day in rabbits (3- to 11-fold by AUC and 43- to 56-fold by C_{mw}). In mice treated orally with 75 mg/kg/day (6- to 27-times the expected exposure at the MRHD based on AUC and greater than 77-times the expected C_{mw}), increased resorptions and decreased live fetuses were observed. One fetus with cleft palate was observed at each dose (15, 45 and 75 mg/kg/day), at an incidence within the background historical range. In rabbits treated orally with 27 mg/kg/day (3- to 11-fold by AUC and 19- to 62-fold by C_{mw}), incompletely ossified sternebrae (retardation of bone development) were observed in fetuses. In rabbits treated by subcutaneous (sc) administration with 4.5 mg/kg/day (3- to 11-fold by AUC and 43- to 53-fold by C_{mw}), aternal toxicity and incompletely ossified sternebrae were observed in fetuses (at an incidence within the background historical range). At 1.5 mg/kg/day (5- to 11-fold by AUC and 43- to 53-fold by C_{mw}), decreased maternal food consumption in the absence of any fetal effects was observed. Oral administration of 30 mg/kg/day fesoterodine to mice in a pre- and post-natal development study resulted in decreased body weight of the dams and delayed ear opening of the pups. No effects were noted on mating and reproduction of the F₁ dams or on the F₂ offspring. There are no adequate and well-controlled studies using Toviaz in pregnant women. Therefore, Toviaz should

There are no adequate and well-controlled studies using Toviaz in pregnant women. Therefore, Toviaz should be used during pregnancy only if the potential benefit outweighs the potential risk to the fetus.

Nursing Mothers

It is not known whether fesoterodine is excreted in human milk. Toviaz should not be administered during nursing unless the potential benefit outweighs the potential risk to the neonate. Pediatric Use

The safety and effectiveness of Toviaz in pediatric patients have not been established

teractions between Toviaz and laboratory tests have not been studied.

Carcinogenesis, Mutagenesis, Impairment of Fertility No evidence of drug-related carcinogenicity was found in 24-month studies with oral administration to mice and rats. The highest tolerated doses in mice (females 45 to 60 mg/kg/day, males 30 to 45 mg/kg/day) correspond to 11- to 19-fold (females) and 4- to 9-fold (males) the estimated human AUC values reached with fesoterodine 8 mg, which is the Maximum Recommended Human Dose (MRHD). In rats, the highest tolerated dose (45 to 60 mg/kg/day) corresponds to 3- to 8-fold (females) and 3- to 14-fold (males), the estimated human AUC at the MRHD.

Fesoterodine had no effect on reproductive function, fertility, or early embryonic development of the fetus at non-maternally toxic doses in mice. The maternal No-Observed-Effect Level (NOEL) and the NOEL for effects on reproduction and early embryonic development were both 15 mg/kg/day. Based on AUC, the systemic exposure was 0.6- to 1.5-fold higher in mice than in humans at the MRHD, whereas based on peak plasma concentrations, the exposure in mice was 5- to 9-fold higher. The Lowest-Observed-Effect Level (LOEL) for maternal toxicity was 45 mg/kg/day.

Pregnancy

nancv Category C

Continued from previous page

"We're not using this to cure cancer," he said in an interview. "This is something that is a service to enhance patients' self-concepts."

Some gynecologists, he said, are "very upset right now" that their patients ask for cosmetic procedures these physicians do not know how to perform. "It's a resentment that they are getting behind."

The idea that the seminars offer "industry secrets," as well as the general lack of solid data about indications and outcomes, is what concerns Dr. Erin Tracy, an ob.gyn. at Massachusetts General Hospital and a faculty member at Harvard Medical School, both in Boston.

"If they truly have procedures that are safe and beneficial for women, I would think they would want to share this data with the scientific community," she said in an interview.

"Women need to be educated that at this point, these procedures are not proven to be safe or effective, and carry risks of bleeding, infection, pain with intercourse, and scar tissue.

"As a profession, we need to sit back and make sure rigorous studies are done," said Dr. Tracy.

She and other critics also questioned potential sexual and long-term complications of aesthetic gynecologic surgery, because the labia minora contain clitoral tissue, and the labia undergo physical changes over a woman's lifetime.

"There may be real risks we just don't know because of a lack of data," she said.

"Papers are coming," promised Dr. Matlock, who said a large, multicenter outcomes study of cosmetic genital procedures has been completed and accepted for publication by the Journal of Sexual Medicine.

Dr. Pelosi also provided a book chapter on "Cosmetogynecology" (a trademarked term) that he said will appear this year in a textbook on minimally invasive gynecologic surgery. The chapter outlines surgical alternatives for reducing the size of the labia minora, advice about removing "loose redundant folds of skin" in the clitoral region, and a brief description of a new vaginal retractor created for vaginal tightening, a procedure with a "postoperative satisfaction rate ... over 98%."

No other data are included.

Up to now, a handful of papers in scientific journals have been dwarfed by coverage of the procedures in women's magazines and the lay press, driving requests for the procedure.

"It's obviously interesting to the media," said Dr. Matlock. "Sex sells."

A recent literature review by a trio of gynecologists from University College in London identified 40 articles on 1,000 cases of labial reduction surgery since 1976 (BJOG 2009;117:20-5).

Of 21 studies containing patient data, 18 described surgical procedures.

However, none was a prospective, randomized controlled study, and 15 were

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that are safe and beneficial

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case reports or case series. Outcomes were generally confined to patient satisfaction, in some cases described anecdotally with such statements as, " e x c e e d i n g l y pleased," "had no

difficulty in wearing tight pants," and "went on to marry a professional golfer."" Twelve papers reported 100% patient satisfaction.

Labial dimensions were not systematically described before and after surgery, nor was a "norm" defined. Authors' perceptions from the studies included descriptions such as "grossly enlarged," "deformed," and "look like spaniel's ears.

Two noncosmetic surgical indications were cited within the papers: Vulvar discomfort caused by genital protrusion and complaints about sexual discomfort were not investigated or objectively assessed.

"This review was initially planned as a systematic review. However, it soon became clear that the available literature was extremely rudimentary and precluded the use of ... recommended methodology," the authors wrote.

"In general, there are no complications," said Dr. Pelosi, although he said papers attempting to objectively quantify such measures are routinely rejected by major ob.gyn. journals for reasons of "bias," not a lack of scientific rigor.

Papers decrying the lack of objective outcomes "miss the point," he said. "Is the patient happy or unhappy? That's what it's all about."

Beyond its scientific criticism, the British paper also commented on advertisements

for labial reduction, which the authors said promote "a homogenized, nonprotruding, and smooth-skinned aesthetic that communicates female sexual immaturity ... distorting public perceptions [and] setting a new benchmark for women."

They went on to comment: "The similarities between cosmetic labial surgery and female genital mutilation are worrying."

Cosmetic gynecologic surgeons vehemently object to both notions: that their patients request a prepubescent labial appearance, and that there are parallels between female genital cosmetic surgery and female genital mutilation.

In interviews, in fact, they characterize the surgery as empowering, the embodiment of the feminist autonomy and control over one's body—the opposite of the culture of male-dominat-

ed social control and coercion underlying female genital mutilation.

"Despite the fact that ob.gyns. are involved their whole lives in dealing with women, [they] have no idea how to meet the needs of female patients," said the elder Dr. Pelosi. "If they are treating anything objective—pain, infections—they are extremely competent, but anything beyond that, they don't want to hear about. They don't listen to what women want," he said.

Feminist literature questions this distinction, suggesting that the same social pressures that perpetuate the cultural belief that girls should be circumcised to preserve their sexuality until marriage drives what they term "mutilation by choice," based on a socially reinforced belief that women's genitals are naturally unattractive and need to be altered to be sexually appealing (Aust. Fem. Stud. 2009;24:233-49).

Frequently the argument is made that women have not seen hundreds of vulvas and labias to compare to their own genital appearance, and should be educated during a surgical consultation about the wide range of normal anatomy, including labia minora widths at midline ranging from 7 to 50 mm (BJOG 2005;112:643-6).

The Web site for Dr. Miklos and Dr. Moore explains that labiaplasty can result in a "sleeker, thinner ... more youthful" appearance of the labia, and "inner lips [that] do not protrude past the labia majora at all, giving them a much more appealing shape and eliminating many of the symptoms of enlarged labia."

To question women's decision to obtain a different aesthetic appearance of their genitals is arrogant and demeaning, said Dr. Matlock.

"Personally, I've treated women from all 50 states and 30 countries and everyone is saying the same thing: 'My gynecologist won't listen to me,' " he said.

"We need to empower women with knowledge, choice, and alternatives," said Dr. Matlock.

Meanwhile, in the Netherlands, Dr. Karen Marieke Paarlberg reviews a booklet of 38 pictures of normal vulvas with patients requesting labiaplasty and discusses with them alternative means of addressing discomfort, if that is an issue. (She notes that few male cyclists or horseback riders undergo surgery to reduce testicular contact during sporting activities.)

"I think that more than 50% of women can be reassured by a doctor who can listen very well and who tries to reassure the woman that she is perfectly normal," she said in an interview.

"Sometimes I perform labia reduction surgery," she said, but only in adult women with serious functional complaints.

She coauthored a proposal for practical guidelines for gynecologists encountering requests for such procedures (J. Psychosom. Obstet. Gynaecol. 2008; 29:230-4).

Dr. Tracy of Harvard said that when she receives such requests, she often finds that "when you probe, you find [psychological] issues that should be addressed," a point emphasized in Dr. Paarlberg's proposal.

Dr. Indman's point is that gynecologists exploit patients' psychological vulnerabilities merely by offering aesthetic procedures, because the decision implies an endorsement of aesthetic deficiencies among normal women.

"We really need to do what's in the best interest of women," said Dr. Indman. "We're all struggling in our practices, but ... if our duty is to provide ethical care, in my opinion we can't do cosmetic cash procedures. I refuse to sell myself."

Skin Color May Affect Visual Detection of Genital Trauma

BY HEIDI SPLETE

BOSTON — The prevalence of genital injuries was significantly higher among white patients than black patients, based on a review of 2,234 women aged 13 years and older who were examined after being raped.

This may be misleading, though, because methods of recognizing these injuries can be ineffectual in black women, said Linda Rossman, M.S.N., of Michigan State University, East Lansing, and her colleagues.

Data from previous studies have shown that direct visualization, contrast media, and colposcopy may be less effective at identifying genital injuries in darker-skinned patients, she said.

"Color awareness may be an important component of the sexual assault forensic examination," she said in a poster presented at the annual meeting of the American College of Emergency Physicians. The researchers reviewed data from 2,234 consecutive female patients who were referred to a community-based Sexual Assault Nurse Examiner program (SANE) from four urban emergency departments during a 10-year period. In this study, genital injury was defined as any visible tissue trauma that could be categorized using the TEARS classification system (tears, ecchymoses, abrasions, redness, and swelling). In this community, 83% of the women were white and 17% were black, with similar demographic characteristics, and the details of the assault cases also were similar. Overall, the prevalence of documented anogenital injuries was significantly higher in whites, compared with blacks (64% vs. 54%). The pattern of anogenital injuries was similar in both groups. The injuries typically involved the fossa navicularis, followed by the posterior fourchette, labia, and hymen, the researchers said. In addition, the prevalence of documented nongenital injuries was significantly higher in whites, compared with blacks (39% vs. 26%).

Lacerations were the most common injuries in all patients, but whites had a significantly greater incidence of documented erythema, compared with blacks, the researchers noted.

Disclosures: None was reported.