

# Double Surgery May Add GI, Wound Complications

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HOLLYWOOD, FLA. — More adverse gastrointestinal events and wound complications may be in store for women who undergo stress incontinence surgery and other procedures concomitantly, according to findings reported at the annual meeting of the American Urogynecologic Society.

“While [we would expect] to see more frequent adverse events occurring in pa-

tients with concomitant surgeries as compared to those who underwent index surgeries only, we wanted to determine which organ systems were more affected by concomitant surgery,” said Dr. Toby Chai, a professor in the urology department at the University of Maryland, Baltimore.

Other types of surgery included posterior colporrhaphy, sacrospinous ligament suspension, uterosacral ligament suspension, sacrocolpopexy, enterocele repair, and hysterectomy.

Previous results from the Stress Incontinence Surgical Treatment Efficacy (SISTER) trial found an overall success rate of 47% with the autologous rectus fascial sling procedure versus a 38% rate of success with the Burch colposuspension after 24 months (N. Engl. J. Med. 2007;35:2198-200).

Stress-type symptoms of urinary incontinence improved for 66% of the sling group, compared with 49% for the Burch group, a significant difference. However, women in the sling group reported more

urinary tract infections, difficulty with voiding, and urge incontinence.

Dr. Chai and his associates conducted a second study as part of the SISTER trial to assess these adverse events further. They found that only wound and gastrointestinal complications had statistically higher rates in the concomitant surgical group at 2 years. There were 7 GI complications in the Burch group and 8 in the sling group, all in women who had undergone another procedure; a total of 24 wound complications occurred, 13 in the Burch group, and 11 in the sling group. Of the 24 events, 22 occurred in the concomitant surgery group.

Up to postoperative week 6, there were 91 reports of cystitis among the 326 women who had a sling procedure, compared with 39 reports among the 329 others who had a Burch procedure. This increased infection rate was associated with a higher rate of clean intermittent self-catheterization (CISC) in the sling group.

At 2 years, there were a total of 290 cystitis events in the sling group, compared

with 206 in the Burch group. “Interestingly, genitourinary complications, including cystitis, were not statistically different between those with and those without concomitant surgeries,” Dr. Chai said in an interview.

“We were surprised by the number of patients, even in the Burch arm, that had cystitis episodes. We of course do not know the preoperative cystitis rate in our population. It is unlikely that this rate was as high as 8%-10%,” he stated, adding that a relatively high number of these patients are treated with oral antibiotics beyond the typical postoperative period.

“The take-home message is that adverse events after Burch and sling are relatively uncommon, except for symptoms of cystitis,” Dr. Chai said.

Investigators at each study site were required to report complications. Therefore, one possible limitation of the study is that adverse event rates were not based on a chart review. Also, cystitis was defined not by a positive urine culture, but by clinical symptoms suggestive of a urinary tract infection that led to an antibiotic prescription.

Whether prophylactic antibiotics will reduce the prevalence of cystitis remains to be seen, Dr. Chai said. In the future, a randomized trial to assess prophylactic antibiotics among patients who require CISC after the sling procedure might be beneficial. However, “there are insufficient data currently to recommend routine antibiotic prophylaxis in all patients who start self-catheterization,” he said.

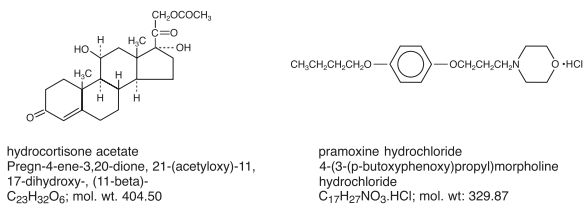
“Overall, the surgeries are safe and ... patients have to balance the risk of these minor complications against their decreased quality of life from stress urinary incontinence,” Dr. Chai concluded. ■

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**CLINICAL PHARMACOLOGY:** Topical corticosteroids share anti-inflammatory, anti-pruritic and vasoconstrictive actions.

The mechanism of anti-inflammatory activity of topical corticosteroids is unclear. Various laboratory methods, including vasoconstrictor assays, are used to compare and predict potencies and/or clinical efficacies of the topical corticosteroids. There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in man.

Pramoxine hydrochloride is a topical anesthetic agent which provides temporary relief from itching and pain. It acts by stabilizing the neuronal membrane of nerve endings with which it comes into contact.

**Pharmacokinetics:** The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.

Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids. Thus, occlusive dressings may be a valuable therapeutic adjunct for treatment of resistant dermatoses. (See DOSAGE AND ADMINISTRATION.)

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into the bile.

**INDICATIONS AND USAGE:** Topical corticosteroids are indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

**CONTRAINDICATIONS:** Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

**PRECAUTIONS: General:** Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients. Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings.

Therefore, patients receiving a large dose of a potent topical steroid applied to a large surface area and under an occlusive dressing should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation tests. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid.

Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids. Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity. (See Precautions-Pediatric Use.)

If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted.

In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly the corticosteroid should be discontinued until the infection has been adequately controlled.

**Information for the Patient:** Patients using topical corticosteroids should receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes.
2. Patients should be advised not to use this medication for any disorder other than for which it was prescribed.
3. The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by the physician.
4. Patients should report any signs of local adverse reactions especially under occlusive dressings.
5. Parents of pediatric patients should be advised not to use tight-fitting diapers or plastic pants on a child being treated in the diaper area, as these garments may constitute occlusive dressings.

**Laboratory Tests:** The following tests may be helpful in evaluating the HPA axis suppression: Urinary free cortisol test  
ACTH stimulation test

**Carcinogenesis, Mutagenesis, and Impairment of Fertility:** Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids. Studies to determine mutagenicity with prednisolone and hydrocortisone have revealed negative results.

**Pregnancy: Teratogenic Effects: Pregnancy Category C:** Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

**Nursing Mothers:** It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable amounts in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities NOT likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman.

**Pediatric Use:** Pediatric patients may demonstrate greater susceptibility to topical corticosteroid induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio.

Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.

**ADVERSE REACTIONS:** The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence:

Burning	Hypertrichosis	Maceration of the skin
Itching	Acneiform eruptions	Secondary infection
Irritation	Hypopigmentation	Skin atrophy
Dryness	Perioral dermatitis	Striae
Folliculitis	Allergic contact dermatitis	Miliaria

**OVERDOSAGE:** Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects. (See PRECAUTIONS.)

**DOSAGE AND ADMINISTRATION:** Topical corticosteroids are generally applied to the affected area as a thin film three to four times daily depending on the severity of the condition. Occlusive dressings may be used for the management of psoriasis or recalcitrant conditions. If an infection develops, the use of occlusive dressings should be discontinued and appropriate antimicrobial therapy instituted.

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