

# Prolapse Surgeries Fail to Help Sexual Function

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CHAMPIONSGATE, FLA. — Despite good surgical outcomes, women undergoing pelvic organ prolapse surgery with or without urinary incontinence repair do not report improved sexual function, primarily because of significant postoperative vaginal pain, according to a prospective study presented at the annual meeting of the Society of Gynecologic Surgeons.

A total of 49 out of 51 women completed the Female Sexual Function Index (FSFI) and other measures before and after vaginal surgery. Vaginal bulging, dryness, and low desire were the chief preoperative complaints. Although some reported dryness and low desire after surgery as well, pain emerged as a significant postoperative barrier to sexual function, Dr. Rachel N. Pauls said.

“It is important to address these issues with patients preoperatively and in the

postoperative period. Our goal is not to introduce problems after surgery to correct vaginal anatomy,” Dr. Pauls said at the meeting, which was jointly sponsored by the American College of Surgeons.

“Prospective studies looking at the effects of surgery on sexual function are sorely needed,” study discussant Dr. Rebecca G. Rogers said. “This one features the use of a validated questionnaire and a high follow-up rate.”

The FSFI addresses sexual frequency, degree of bother from sexual symptoms, and barriers to sexual activity. Participants also completed short forms of the Urogenital Distress Inventory (UDI) and the Incontinence Impact Questionnaire (IIQ).

Nearly all respondents, 48 of 49, reported they were sexually active. Mean age was 54 years and mean body mass index was 27 kg/m<sup>2</sup>. Twenty-five women had anti-incontinence surgery at the time of their vaginal repairs.

At 6 months postoperatively, participants were mailed questionnaires and asked to describe any changes to sexual function.

Space was included for women to add comments. Ten women listed improvements and 19 listed problems, including

5 who said they had lower sexual desire. “A total of 12 reported vaginal pains, ranging from mild in 3 to severe in 9,” said Dr. Pauls, a urogynecologist in the department of obstetrics, Good Samaritan Hospital, Cincinnati.

The surgeries yielded significant improvements in prolapse stage, UDI, and IIQ scores. However, there were no differences in the FSFI domain or total scores before and after surgery, Dr. Pauls said. “A generic quality-of-life questionnaire may not be sensitive enough for assessing sexual function in women with prolapse and/or incontinence,” said Dr. Rogers, director of the division of urogynecology, University of New Mexico Health Sciences Center, Albuquerque.

Despite no overall change, Dr. Rogers asked how many individual participants had improved or worsened FSFI scores. Dr. Pauls replied that 47% reported a deterioration, a mean 5.4 points difference, and 53% noted an improvement, a mean 3.7 points difference. “And those who deteriorated had a higher mean age of 56 vs. 50 years,” she added.

Dr. Rogers asked if the researchers accounted for differences among the 22% who had a bilateral salpingo-oophorectomy at time of surgery. “We did not control for this factor, but the scores for women who had BSO and those who did not were not significantly different,” Dr. Pauls said.

A follow-up period that may have been too short for symptom resolution is a possible limitation of the study, Dr. Pauls said. Lack of vaginal diameter measurement and omission of prolapse and bowel function questionnaires are other potential shortcomings.

A meeting attendee asked if Dr. Pauls and her associates made any clinical recommendations based on the reports of vaginal dryness or pain. She replied, “This was a postal survey, but we did follow-up with those who reported pain.” ■

## TWINRIX® [Hepatitis A Inactivated & Hepatitis B (Recombinant) Vaccine]

The following is a brief summary only; see full prescribing information for complete product information.

**INDICATIONS AND USAGE:** TWINRIX is indicated for active immunization of persons 18 years of age or older against disease caused by hepatitis A virus and infection by all known subtypes of hepatitis B virus.

**CONTRAINDICATIONS:** Hypersensitivity to any component of the vaccine, including yeast and neomycin, is a contraindication (see DESCRIPTION in full prescribing information). This vaccine is contraindicated in patients with previous hypersensitivity to TWINRIX or monovalent hepatitis A or hepatitis B vaccines.

**WARNINGS:** There have been rare reports of anaphylaxis/anaphylactoid reactions following routine clinical use of TWINRIX. (See ADVERSE REACTIONS, Postmarketing Reports.) The tip cap and the rubber plunger of the needleless prefilled syringes contain dry natural latex rubber that may cause allergic reactions in latex sensitive individuals. The vial stopper is latex free. Hepatitis A and hepatitis B have relatively long incubation periods. TWINRIX may not prevent hepatitis A or hepatitis B infection in individuals who have an unrecognized hepatitis A or hepatitis B infection at the time of vaccination. Additionally, it may not prevent infection in individuals who do not achieve protective antibody titers.

**PRECAUTIONS: General:** Prior to immunization with TWINRIX, the patient's current health status and medical history should be reviewed. The physician should review the patient's immunization history for possible vaccine sensitivity, previous vaccination-related adverse reactions and occurrence of any adverse-event-related symptoms and/or signs, in order to determine the existence of any contraindication to immunization with TWINRIX and to allow an assessment of benefits and risks. Appropriate medical treatment and supervision should be readily available for immediate use in case of a rare anaphylactic reaction following the administration of the vaccine. Epinephrine injection (1:1,000) and other appropriate agents used for the control of immediate allergic reactions must be immediately available. As with other vaccines, delay administration, if possible, in persons with a moderate or severe acute illness. Minor illnesses such as mild upper respiratory infections with or without low grade fever are not contraindications. TWINRIX should be given with caution in persons with bleeding disorders such as hemophilia or thrombocytopenia and in persons on anticoagulant therapy, with steps taken to avoid the risk of hematoma following the injection. A separate, sterile syringe and needle or a sterile disposable unit should be used for each patient to prevent the transmission of other infectious agents from person to person. Needles should be disposed of properly and should not be recapped. As with any vaccine, if administered to immunosuppressed persons, including individuals receiving immunosuppressive therapy, the expected immune response may not be obtained.

**Multiple Sclerosis:** Results from 2 clinical studies indicate that there is no association between hepatitis B vaccination and the development of multiple sclerosis, and that vaccination with hepatitis B vaccine does not appear to increase the short-term risk of relapse in multiple sclerosis.

**Information for Vaccine Recipients:** Vaccine recipients should be informed by their healthcare provider of the potential benefits and risks of immunization with TWINRIX. When educating vaccine recipients regarding potential side effects, clinicians should emphasize that components of TWINRIX cannot cause hepatitis A or hepatitis B infection. Vaccine recipients should be instructed to report any severe or unusual adverse reactions to their healthcare provider. The vaccine recipients should be given the Vaccine Information Statements, which are required by the National Childhood Vaccine Injury Act of 1986 to be given prior to immunization. These materials are available free of charge at the CDC website ([www.cdc.gov/nip](http://www.cdc.gov/nip)). The Vaccine Adverse Events Reporting System (VAERS) toll-free number is 1-800-822-7967. Reporting forms may also be obtained at the VAERS website at [www.vaers.hhs.gov](http://www.vaers.hhs.gov).

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** TWINRIX has not been evaluated for its carcinogenic potential, mutagenic potential, or potential for impairment of fertility. **Pregnancy:** Pregnancy Category C: Animal reproduction studies have not been conducted with TWINRIX. It is also not known whether TWINRIX can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. TWINRIX should be given to a pregnant woman only if clearly indicated (see INDICATIONS AND USAGE). **Pregnancy Exposure Registry:** Healthcare providers are encouraged to register pregnant women who receive TWINRIX in the GlaxoSmithKline vaccination pregnancy registry by calling 1-888-825-5249. **Nursing Mothers:** It is not known whether TWINRIX is excreted in human milk. Because many drugs are excreted in human milk, use caution when administering TWINRIX to a nursing woman. **Pediatric Use:** Safety and effectiveness in pediatric patients below the age of 18 years have not been established. **Geriatric Use:** Clinical studies of TWINRIX did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

Table 1. Rate of Adverse Events Reported After Administration of TWINRIX or ENGERIX-B and HAVRIX

| Adverse Event | TWINRIX      |              |              | ENERGIX-B            |              |              | HAVRIX       |              |
|---------------|--------------|--------------|--------------|----------------------|--------------|--------------|--------------|--------------|
|               | Dose 1       | Dose 2       | Dose 3       | Dose 1               | Dose 2       | Dose 3       | Dose 1       | Dose 2       |
| Local         | (N=385)<br>% | (N=382)<br>% | (N=374)<br>% | (N=382)<br>%         | (N=376)<br>% | (N=369)<br>% | (N=382)<br>% | (N=369)<br>% |
| Soreness      | 37           | 35           | 41           | 41                   | 25           | 30           | 53           | 47           |
| Redness       | 8            | 9            | 11           | 6                    | 7            | 9            | 7            | 9            |
| Swelling      | 4            | 4            | 6            | 3                    | 5            | 5            | 5            | 5            |
|               |              |              |              |                      |              |              |              |              |
| Adverse Event | TWINRIX      |              |              | ENERGIX-B and HAVRIX |              |              |              |              |
|               | Dose 1       | Dose 2       | Dose 3       | Dose 1               | Dose 2       | Dose 3       |              |              |
| General       | (N=385)<br>% | (N=382)<br>% | (N=374)<br>% | (N=382)<br>%         | (N=376)<br>% | (N=369)<br>% |              |              |
| Headache      | 22           | 15           | 13           | 19                   | 12           | 14           |              |              |
| Fatigue       | 14           | 13           | 11           | 14                   | 9            | 10           |              |              |
| Diarrhea      | 5            | 4            | 6            | 5                    | 3            | 3            |              |              |
| Nausea        | 4            | 3            | 2            | 7                    | 3            | 5            |              |              |
| Fever         | 4            | 3            | 2            | 4                    | 2            | 4            |              |              |
| Vomiting      | 1            | 1            | 0            | 1                    | 1            | 1            |              |              |

**ADVERSE REACTIONS:** Because clinical trials are conducted under widely varying conditions, adverse event rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine, and may not reflect the rates observed in practice. As with any vaccine, there is the possibility that broad use of TWINRIX could reveal adverse events not observed in clinical trials. The safety of TWINRIX has been evaluated in clinical trials involving the administration of approximately 7,500 doses to more than 2,500 individuals. Of 773 volunteers who participated in a US comparative trial, 389 subjects received at least 1 dose of TWINRIX (0-, 1-, and 6-month schedule) and 384 received at least 1 dose each of ENGERIX-B® [Hepatitis B Vaccine (Recombinant)] and HAVRIX® (Hepatitis A Vaccine, Inactivated) as separate injections. Solicited local adverse events reported after administration of TWINRIX, compared with adverse events reported after the administration of ENGERIX-B or HAVRIX, are shown in the table above.

Adverse reactions seen with TWINRIX were similar to those observed after vaccination with the monovalent components. The frequency of solicited adverse events did not increase with successive doses of TWINRIX. Most events reported were considered by the subjects as mild and self-limiting and did not last more than 48 hours. In a clinical trial in which TWINRIX was given on a 0-, 7-, and 21- to 30-day schedule followed by a booster dose at 12 months, solicited local or general adverse events were comparable to those seen in other clinical trials of TWINRIX given on a 0-, 1-, and 6-month schedule. Among 2,299 subjects in 14 clinical trials, the following adverse experiences were reported to occur within 30 days following vaccination with the frequency shown below. Adverse experiences within 30 days of vaccination in the US clinical trial of TWINRIX given on a 0-, 7-, and 21- to 30-day schedule followed by a booster dose at 12 months were similar to those reported in other clinical trials and post marketing surveillance.

**Incidence 1% to 10% of Injections: Local Reactions at Injection Site:** Induration. **Respiratory System:** Upper respiratory tract infections.

**Incidence <1% of Injections: Local Reactions at Injection Site:** Pruritus, ecchymoses. **Body as a Whole:** Sweating, weakness, flushing, influenza-like symptoms. **Cardiovascular System:** Syncope. **Gastrointestinal System:** Abdominal pain, anorexia, vomiting. **Musculoskeletal System:** Arthralgia, myalgia, back pain. **Nervous System:** Migraine, paresthesia, vertigo, somnolence, insomnia, irritability, agitation, dizziness. **Respiratory System:** Respiratory tract illnesses. **Skin and Appendages:** Rash, urticaria, petechiae, erythema.

**Incidence <1% of Injections, Seen in Clinical Trials With HAVRIX® and/or ENGERIX-B®: Body as a Whole:** Tingling.<sup>a</sup> **Cardiovascular System:** Hypotension.<sup>a</sup> **Gastrointestinal:** Constipation,<sup>a</sup> dysgeusia.<sup>a</sup> **Hematologic/lymphatic:** Lymphadenopathy.<sup>a,b</sup> **Musculoskeletal System:** Elevation of creatine phosphokinase.<sup>a</sup> **Nervous System:** Hypertonic episode,<sup>a</sup> photophobia.<sup>a</sup>

**Postmarketing Reports:** Worldwide voluntary reports of adverse events received for TWINRIX, HAVRIX, and/or ENGERIX-B since market introduction of these vaccines are listed below. These lists include serious events or events which have suspected causal connections to components of these or other vaccines or drugs. Because these events are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure.

**Postmarketing Reports With TWINRIX: Body as a Whole:** Anaphylaxis/anaphylactoid reactions and allergic reactions. **Hypersensitivity:** Arthritis, serum sickness-like syndrome days to weeks after vaccination including arthralgia/arthritis (usually transient), fever, urticaria, erythema multiforme, ecchymoses, and erythema nodosum. **Cardiovascular System:** Tachycardia/palpitations. **Skin and Appendages:** Erythema multiforme, hyperhidrosis, angioedema, eczema, herpes zoster, erythema nodosum, alopecia. **Gastrointestinal System:** Jaundice, hepatitis, abnormal liver function tests, dyspepsia. **Hematologic/lymphatic:** Thrombocytopenia. **Nervous System:** Convulsions, paresis, encephalopathy, neuropathy, myelitis, Guillain-Barré syndrome, multiple sclerosis, Bell's palsy, transverse myelitis, optic neuritis. **Respiratory System:** Dyspnea, bronchospasm including asthma like symptoms. **Special Senses:** Conjunctivitis, visual disturbances, tinnitus, earache.

**Postmarketing Reports With HAVRIX and/or ENGERIX-B:** Worldwide voluntary reports of adverse events received for HAVRIX and/or ENGERIX-B but not already reported for TWINRIX are listed below. **Hypersensitivity:** Stevens-Johnson syndrome.<sup>a</sup> **Special Senses:** Keratitis.<sup>b</sup> **Other:** Congenital abnormality.<sup>a</sup>

<sup>a</sup>Following HAVRIX; <sup>b</sup>Following ENGERIX-B; <sup>\*\*\*</sup>Following either HAVRIX or ENGERIX-B. Manufactured by **GlaxoSmithKline Biologicals**, Rixensart, Belgium Distributed by **GlaxoSmithKline**, Research Triangle Park, NC 27709 TWINRIX, HAVRIX, and ENGERIX-B are registered trademarks of GlaxoSmithKline. BRS-TW:L7

Reference: 1. Connor BA, Blatter MM, Beran J, Zou B, Trofa AF. Rapid and sustained immune response against hepatitis A and B achieved with combined vaccine using an accelerated administration schedule. *J Travel Med.* 2007;14:9-15.

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