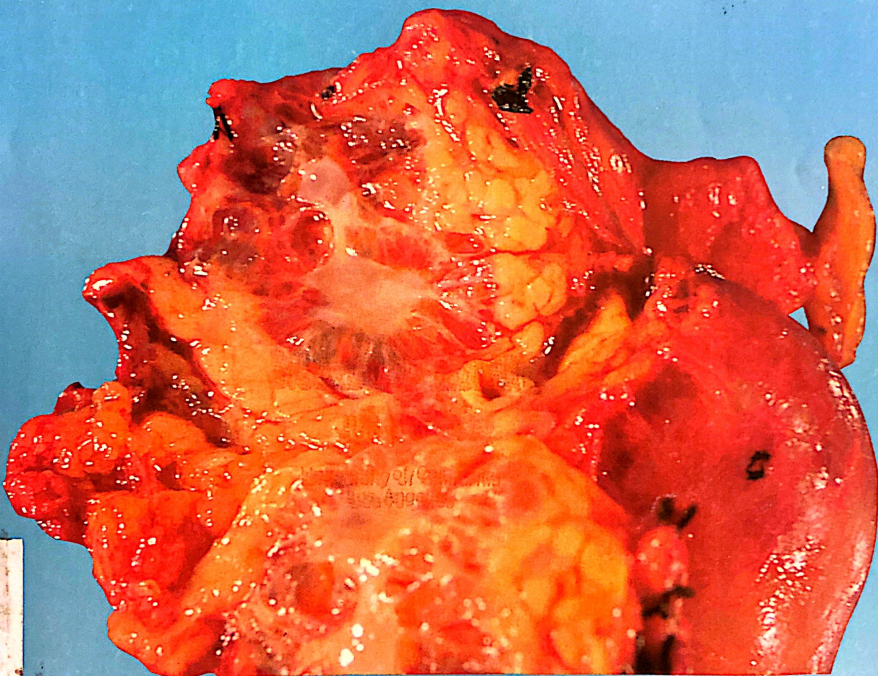


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Symposium

THYMECTOMY FOR MYASTHENIA GRAVIS

Solventum Corp. v. Wound Healing Techs., LLC; No IPR2025-01042

1 of 11

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Use complete prescribing information in SK&F LAB CO. literature or PDR. The following is a brief summary.

Contraindications: "Tagamet" is contraindicated for patients known to have hypersensitivity to the product.

Precautions: Rare instances of cardiac arrhythmias and hypotension have been reported following the rapid administration of "Tagamet" HCl (brand of cimetidine hydrochloride) by intravenous bolus.

Symptomatic response to "Tagamet" therapy does not preclude the presence of a gastric malignancy. There have been rare reports of transient healing of gastric ulcers despite subsequently documented malignancy.

Reversible confusional states have been observed on occasion, predominantly in severely ill patients.

"Tagamet" has been reported to reduce the hepatic metabolism of warfarin-type anticoagulants, phenytoin, propranolol, chlorazepate, diazepam, certain tricyclic antidepressants, lidocaine, theophylline and metoprolol. Clinically significant effects have been reported with warfarin anticoagulants; therefore, close monitoring of prothrombin time is recommended, and adjustment of the anticoagulant dose may be necessary when "Tagamet" is administered concomitantly. Interaction with phenytoin, lidocaine and theophylline has also been reported to produce adverse clinical effects.

However, a crossover study in healthy subjects receiving either "Tagamet" 300 mg. q.i.d. or 800 mg. h.s. concomitantly with a 300 mg. b.i.d. dosage of theophylline (Theo-Dur, Key Pharmaceuticals, Inc.) demonstrated less alteration in steady-state theophylline peak serum levels with the 800 mg. h.s. regimen, particularly in subjects aged 54 years and older. Data beyond ten days are not available. (Note: All patients receiving theophylline should be monitored appropriately, regardless of concomitant drug therapy.)

In a 24-month toxicity study in rats, at dose levels approximately 8 to 48 times the recommended human dose, benign Leydig cell tumors were seen. These were common in both the treated and control groups, and the incidence became significantly higher only in the aged rats receiving "Tagamet".

A weak antiandrogenic effect has been demonstrated in animals. In human studies, "Tagamet" has been shown to have no effect on spermatogenesis, sperm count, motility, morphology or in vitro fertilizing capacity.

Pregnancy Category B: Reproduction studies have been performed in rats, rabbits and mice at doses up to 40 times the normal human dose and have revealed no evidence of impaired fertility or harm to the fetus due to "Tagamet". There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproductive studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Lack of experience to date precludes recommending "Tagamet" for use in children under 16 unless anticipated benefits outweigh potential risks; generally, nursing should not be undertaken by patients taking the drug since cimetidine is secreted in human milk.

Adverse Reactions: Diarrhea, dizziness, somnolence, headache. Reversible confusional states (e.g., mental confusion, agitation, psychosis, depression, anxiety, hallucinations, disorientation), predominantly in severely ill patients, have been reported. Reversible impotence in patients with pathological hypersecretory disorders receiving "Tagamet", particularly in high doses, for at least 12 months, has been reported. Incidence of impotence in large-scale surveillance studies at regular doses has not exceeded that commonly reported in the general population. Gynecomastia has been reported in patients taking for one month or longer.

Decreased white blood cell counts in "Tagamet"-treated patients (approximately 1 per 100,000 patients), including agranulocytosis (approximately 3 per million patients), have been reported, including a few reports of recurrence on challenge. Most of these reports were in patients who had serious concomitant illnesses and received drugs and/or treatment known to produce neutropenia. Thrombocytopenia (approximately 3 per million patients) and, very rarely, cases of aplastic anemia have also been reported. Increased serum transaminase has been reported. Reversible adverse hepatic effects, cholestatic or mixed cholestatic-hepatocellular in nature, have been reported rarely. Because of the predominance of cholestatic features, severe parenchymal injury is considered highly unlikely. A single case of biopsy-proven perportal hepatitis/fibrosis in a patient receiving "Tagamet" has been reported. Increased plasma creatinine has been reported. Rare cases of fever, interstitial nephritis, urinary retention, pancreatitis and allergic reactions, including anaphylaxis and hypersensitivity vasculitis, have been reported. Rare cases of bradycardia, tachycardia and A-V heart block have been reported with H₂-receptor antagonists.

Reversible arthralgia, myalgia and exacerbation of joint symptoms in patients with preexisting arthritis have been reported rarely. Rare cases of polymyositis have been reported, but no causal relationship has been established. Mild rash and, very rarely, cases of severe generalized skin reactions (e.g., Stevens-Johnson syndrome, epidermal necrolysis, erythema multiforme, exfoliative dermatitis and generalized exfoliative erythrodermal) have been reported with H₂-receptor antagonists. Reversible alopecia has been reported very rarely.

How Supplied: Tablets: 200 mg. tablets in bottles of 100; 300 mg. tablets in bottles of 100 and Single Unit Packages of 100 (intended for institutional use only); 400 mg. tablets in bottles of 60 and Single Unit Packages of 100 (intended for institutional use only); and 800 mg. tablets in bottles of 30 and Single Unit Packages of 100 (intended for institutional use only).

Usual Dosage: 300 mg./5 mL., in 8 fl. oz. (237 mL.) amber glass bottles and in single-dose units (300 mg./5 mL.), in packages of 10 (intended for institutional use only).

Injectons: Tablets 300 mg./2 mL. in single-dose vials, in packages of 10 and 30, and in 6 mL. multiple-dose vials, in packages of 10 and 25.

Prefilled Syringes: 300 mg./2 mL. in single-dose prefilled disposable syringes.

Single-Dose Premixed Plastic Containers: 300 mg. in 50 mL. of 0.9% Sodium Chloride in single-dose plastic containers, in packages of 4 units. No preservative has been added.

Exposure of the premixed product to excessive heat should be avoided. It is recommended the product be stored at controlled room temperature. Brief exposure up to 40°C does not adversely affect the premixed product.

ADD-Vantage®: Vials 300 mg./2 mL. in single-dose ADD-Vantage® Vials, in packages of 25.

"Tagamet" HCl (brand of cimetidine hydrochloride) injection premixed in single-dose plastic containers is manufactured for SK&F Lab Co. by Baxter Healthcare Corporation, Deerfield, IL 60015.

*ADD-Vantage® is a trademark of Abbott Laboratories.

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INDICATIONS AND USAGE: For the relief of moderate to moderately severe pain.

CONTRAINDICATIONS: Hypersensitivity to acetaminophen or hydrocodone.

WARNINGS:
Allergic-Type Reactions: VICODIN/VICODIN ES tablets contain sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people.

Respiratory Depression: At high doses or in sensitive patients, hydrocodone may produce dose-related respiratory depression.

Head Injury and Increased Intracranial Pressure: The respiratory depressant effects of opioids may be exaggerated in patients with head injuries or the capacity to elevate cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury, other intracranial lesions or a preexisting increase in intracranial pressure. Furthermore, narcotics produce adverse reactions which may obscure the clinical course of patients with head injuries.

Acute Abdominal Conditions: The administration of narcotics may obscure the diagnosis or clinical course of patients with acute abdominal conditions.

PRECAUTIONS:
Special Risk Patients: VICODIN/VICODIN ES tablets should be used with caution in elderly or debilitated patients and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, prostatic hypertrophy or urethral stricture.
Cough Reflex: Hydrocodone suppresses the cough reflex; as with all narcotics, caution should be exercised when VICODIN/VICODIN ES tablets are used postoperatively and in patients with pulmonary disease.
Drug Interactions: Patients receiving other narcotic analgesics, antipsychotics, anxiolytics, sedatives, or other CNS depressants (including alcohol) concomitantly with VICODIN/VICODIN ES tablets may exhibit an additive CNS depression. The use of MAO inhibitors or tricyclic antidepressants with hydrocodone preparation may increase the effect of either the hydrocodone or hydrocodone. The concurrent use of anticholinergics with hydrocodone may produce paralytic ileus.

Usage in Pregnancy:
Teratogenic Effects: Pregnancy Category C. Hydrocodone has been shown to be teratogenic in hamsters when given in doses 700 times the human dose. There are no adequate and well-controlled studies in pregnant women. VICODIN/VICODIN ES tablets should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nonteratogenic effects: Babies born to mothers who have been taking opioids regularly prior to delivery will be physically dependent. The withdrawal signs include irritability and excessive crying, tremors, hyperactive reflexes, increased respiratory rate, increased stools, sneezing, yawning, vomiting, and fever.

Labor and Delivery: Administration of VICODIN/VICODIN ES tablets to the mother shortly before delivery may result in some degree of respiratory depression in the newborn, especially if higher doses are used.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from VICODIN/VICODIN ES tablets, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS:
The most frequently observed adverse reactions include light-headedness, dizziness, sedation, nausea and vomiting. These effects seem to be more prominent in ambulatory than in nonambulatory patients and some of these adverse reactions may be alleviated if the patient lies down. Other adverse reactions include:

Central Nervous System: Drowsiness, mental clouding, lethargy, impairment of mental and physical performance, anxiety, fear, dysphoria, psychic dependence and mood changes.

Gastrointestinal System: The antiemetic phenothiazines are useful in suppressing the nausea and vomiting which may occur (see above); however, some phenothiazine derivatives seem to be antianalgesic and to increase the amount of narcotic required to produce pain relief, while other phenothiazines reduce the amount of narcotic required to produce a given level of analgesia. Prolonged administration of VICODIN/VICODIN ES tablets may produce constipation.

Genitourinary System: Urinary spasm, spasm of vesical sphincters and urinary retention have been reported.

Respiratory Depression: Hydrocodone bitartrate may produce dose-related respiratory depression by acting directly on the brain stem respiratory center. Hydrocodone also affects the center that controls respiratory rhythm, and may produce irregular and periodic breathing. If significant respiratory depression occurs, it may be antagonized by the use of naloxone hydrochloride. Apply other supportive measures when indicated.

DRUG ABUSE AND DEPENDENCE:
VICODIN/VICODIN ES tablets are subject to the Federal Controlled Substance Act (Schedule III). Psychic dependence, physical dependence, and tolerance may develop upon repeated administration of narcotics; therefore, VICODIN/VICODIN ES tablets should be prescribed and administered with caution.

OVERDOSEAGE:
Acetaminophen Signs and Symptoms: In acute acetaminophen overdose, dose-dependent, potentially fatal hepatic necrosis is the most serious adverse effect. Renal tubular necrosis, hypoglycemic coma, and thrombocytopenia may also occur. Early symptoms following a potentially hepatotoxic overdose may include: nausea, vomiting, diaphoresis and general malaise. Clinical and laboratory evidence of hepatic toxicity may not be apparent until 48 to 72 hours post-ingestion.

Hydrocodone Signs and Symptoms: Serious overdose with hydrocodone is characterized by respiratory depression (a decrease in respiratory rate and/or tidal volume, Cheyne-Stokes respiration, cyanosis), extreme somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, and sometimes bradycardia and hypotension. In severe overdose, apnea, circulatory collapse, cardiac arrest and death may occur.

Solventum Corp. EX-1016
TOP of NEW PATENT
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University of North Dakota School of Medicine



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ZANTAC® Injection Premixed
(ranitidine hydrochloride)

The following is a brief summary only. Before prescribing, see complete prescribing information in ZANTAC® Injection Premixed product labeling.

INDICATIONS AND USAGE: ZANTAC® Injection and ZANTAC® Injection Premixed are indicated in some hospitalized patients with pathological hypersecretory conditions or intractable duodenal ulcers, or as an alternative to the oral dosage form for short-term use in patients who are unable to take oral medication.

CONTRAINDICATIONS: ZANTAC® Injection and ZANTAC® Injection Premixed are contraindicated for patients known to have hypersensitivity to the drug.

PRECAUTIONS: General: 1. Symptomatic response to ZANTAC® therapy does not preclude the presence of gastric malignancy.

2. Since ZANTAC is excreted primarily by the kidney, dosage should be adjusted in patients with impaired renal function (see DOSAGE AND ADMINISTRATION). Caution should be observed in patients with hepatic dysfunction since ZANTAC is metabolized in the liver.

Drug Interactions: Although ZANTAC has been reported to bind weakly to cytochrome P-450 in vitro, recommended doses of the drug do not inhibit the action of the cytochrome P-450-linked oxygenase enzymes in the liver. However, there have been isolated reports of drug interactions that suggest that ZANTAC may affect the bioavailability of certain drugs by some mechanism as yet unidentified (eg, a pH-dependent effect on absorption or a change in volume of distribution).

Cardiogenesis, Mutagenesis, Impairment of Fertility: There was no indication of tumorigenic or carcinogenic effects in lifespan studies in mice and rats at oral doses up to 2,000 mg/kg/day.

Ranitidine was not mutagenic in standard bacterial tests (*Salmonella*, *Escherichia coli*) for mutagenicity at concentrations up to the maximum recommended for these assays.

In a dominant lethal assay, a single oral dose of 1,000 mg/kg to male rats was without effect on the outcome of two matings per week for the next nine weeks.

Pregnancy: Teratologic Effects: Pregnancy Category B: Reproduction studies have been performed in rats and rabbits at oral doses up to 160 times the human oral dose and have revealed no evidence of impaired fertility or harm to the fetus due to ZANTAC. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: ZANTAC is secreted in human milk. Caution should be exercised when ZANTAC is administered to a nursing mother.

Pediatric Use: Safety and effectiveness in children have not been established.

Use in Elderly Patients: Oral healing rates in elderly patients (65 to 82 years of age) treated with oral ZANTAC were no different from those in younger age groups. The incidence rates for adverse events and laboratory abnormalities were also not different from those seen in other age groups.

ADVERSE REACTIONS: Transient pain at the site of intramuscular injection has been reported. Transient local burning or itching has been reported with intravenous administration of ZANTAC.

The following have been reported as events in clinical trials or in the routine management of patients treated with oral ZANTAC. The relationship to ZANTAC therapy has been unclear in many cases. Headache, sometimes severe, seems to be related to ZANTAC administration.

Central Nervous System: Rarely, malaise, dizziness, somnolence, insomnia, and vertigo. Rare cases of reversible mental confusion, agitation, depression, and hallucinations have been reported, predominantly in severely ill elderly patients. Rare cases of reversible blurred vision suggestive of a change in accommodation have been reported.

Cardiovascular: Rare reports of tachycardia, bradycardia, and premature ventricular beats. **Gastrointestinal:** Constipation, diarrhea, nausea/vomiting, and abdominal discomfort/pain. **Hematologic:** In normal volunteers, SGPT values were increased to at least twice the pretreatment levels in 6 of 12 subjects receiving 100 mg qid IV for seven days, and in 4 of 24 subjects receiving 50 mg qid IV for five days. With oral administration there have been occasional reports of reversible hepatitis, hepatocellular or hepatocellular or mixed, with or without jaundice.

Musculoskeletal: Rare reports of arthralgias.

Hematologic: Reversible blood count changes (leukopenia, granulocytopenia, and thrombocytopenia) have occurred in a few patients. Rare cases of agranulocytosis or of pancytopenia, sometimes with marrow hypoplasia, have been reported.

Endocrine: Controlled studies in animals and man have shown no stimulation of any pituitary hormone by ZANTAC and no antiandrogenic activity, and cimetidine-induced gynecomastia and impotence in hypersecretory patients have resolved when ZANTAC has been substituted. However, occasional cases of gynecomastia, and loss of libido have been reported in male patients receiving ZANTAC, but the incidence did not differ from that in the general population.

Idiosyncratic: Rash, including rare cases suggestive of mild erythema multiforme, and, rarely, alopecia.

Other: Rare cases of hypersensitivity reactions (eg, bronchospasm, fever, rash, eosinophilia) and small increases in serum creatinine.

OVERDOSAGE: Information concerning possible overdosage and its treatment appears in the full prescribing information.

DOSAGE AND ADMINISTRATION: (See complete prescribing information in ZANTAC® Injection/Premixed product labeling.)

Dose Adjustment for Patients with Impaired Renal Function: On the basis of experience with a group of subjects with severely impaired renal function treated with ZANTAC, the recommended dosage in patients with a creatinine clearance less than 50 ml/min is 50 mg b.i.d. to 24 hours after the patient's creatinine is known, the frequency of dosing may be increased to every 12 hours or even further with caution. Hemodialysis reduces the level of circulating ranitidine. Ideally, the dosage schedule should be adjusted so that the timing of a scheduled dose coincides with the end of hemodialysis.

HOW SUPPLIED: ZANTAC® Injection, 25 mg/ml, containing phenol 0.5% as preservative, is available as follows:

NDC 0173-0362-38 2-ml single-dose vials (Tray of 10)

NDC 0173-0363-39 10-ml multi-dose vials (Singles)

NDC 0173-0363-00 40-ml Pharmacy Bulk Package (Singles)

NDC 0173-0362-00 2-ml single-dose, prefilled, disposable syringes (Singles)

Store below 30°C (86°F). Protect from light.

ZANTAC® Injection Premixed in 0.45% Sodium Chloride, 0.5 mg/ml, is available as a sterile premixed solution for IV administration in 100-ml single-dose flexible plastic containers (NDC 0173-0407-00). It contains no preservatives.

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Protection from freezing. It is recommended that the product be stored at room temperature (25°C); however, brief exposure up to 40°C does not adversely affect the product.

Glaxo

ZANTAC® Injection in vials:

Glaxo Inc., Research Triangle Park, NC 27709

ZANTAC® Injection in prefilled syringes:

Manufactured for Glaxo Inc., Research Triangle Park, NC 27709

by Survival Technology, Inc., Bethesda, MD 20814

ZANTAC® Injection Premixed:

Manufactured for Glaxo Inc., Research Triangle Park, NC 27709

by Abbott Laboratories, North Chicago, IL 60064

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April 1988

Outstanding references from G & S!

SURGERY OF THE VEINS

Edited by

John J. Bergan, M.D.

James S. T. Yao, M.D., Ph.D.

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Surgery of the Veins is recommended to practicing vascular and general surgeons, interested internists, and general orthopedic surgeons.

CONTENTS (Section Heads Only): Basic Considerations. Diagnostic Studies. Acute Deep-Vein Thrombosis. Surgery of Chronic Venous Insufficiency. Surgery for Inherent Venous Insufficiency. Upper Extremity Venous Thrombosis. Surgery of the Vena Cava. Surgical Management of Venous Thromboembolism. Preventive Measures for Acute Deep-Vein Thrombosis. Supportive Measures after Deep-Vein Thrombosis.

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Effective management of incisional and cutaneous fistulae with closed suction wound drainage

Mark E. Chariker, M.D., Katherine F. Jeter, Ed.D. ET
Tess E. Tintle, BSN ET, John E. Bottsford, Jr., M.D.

INTRODUCTION

Management of incisional and cutaneous fistulae is a multifaceted problem requiring a team approach and attention to detail. Nutritional requirements, quantitative and qualitative analysis of fistula drainage, radiographic localization of the fistula, appropriate treatment of sepsis, management of the cutaneous aspect of the fistula, and local skin care are basic tenets defined in the literature.¹⁻⁵

Wound management in patients with ventral incisions complicated by enterocutaneous fistula has been a particularly challenging problem. Containment of the effluent is technically difficult due to the wound configuration and abdominal contour. Since the advent of enterostomal therapy at the Cleveland Clinic in the 1950s, most draining wounds have been managed with ostomy pouches or, more recently, large sophisticated drainage pouches made specifically for wound management.

At our institution, in conjunction with the enterostomal therapy (ET) service, we have devised a closed suction wound drainage system that 1) is effective in collecting drainage from the most

difficult sites, 2) obviates skin damage, 3) improves wound granulation and contraction, and 4) minimizes the dressing and nursing requirements and dramatically reduces the cost associated with wound management and containment.

Similar systems have been described by Montgomery, Everett, and Betancourt; however, these clinicians have not attempted to design a dressing that conforms to the wound bed.⁶⁻⁸ We believe this conformation and the effectiveness of the continuous closed suction are critical to fistula closure and wound contraction. Perhaps the most important facet of our system is its ability to continually remove the effluent from the wound bed. By removal of this effluent, we have noted a profound decrease in the inflammatory response and the localized tissue necrosis. This aspect of our system, in conjunction with an occlusive dressing, maintains adequate hydration of the tissue, preventing eschar formation. The effect of this system is to decrease the inflammatory phase of wound healing and prevent eschar formation, a mechanical barrier to wound healing.⁹ This, in turn, decreases the degree of fibroplasia, i.e. granulation tissue. The result is to increase the rate of reepithelialization.

MATERIALS AND METHODS

When a fistula has been detected, collaboration
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continued

Dr. Mark Chariker is a resident in surgery and Dr. John E. Bottsford, Jr. is director of education, Department of Surgery; Katherine F. Jeter is clinical assistant professor of urology and staff affiliate in enterostomal therapy, and Tess E. Tintle is enterostomal therapy nurse, Spartanburg Regional Medical Center, Spartanburg, South Carolina.

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between the surgical staff and the enterostomal therapy service begins. The surgeon and the ET team assess the wound and devise a treatment plan. The ET nurse becomes responsible for the initial placement of the closed suction system, monitoring its efficacy, and changing it.

The following dressing package has been developed by our ET service: one Jackson-Pratt Mini-Snyder hemovac drain, one two by two inch square, four by four inch gauze squares, normal saline, one small "Christmas tree" adapter, skin sealant, transparent adhesive film dressing to seal wound site, Stomahesive Paste, pink tape, continuous suction system.

The closed wound drainage system is created in the following manner and illustrated in Fig. 1-4:

- 1) Irrigate wound bed thoroughly with normal saline via a 30ml syringe with a 19-gauge needle.

- 2) Open completely one two by two inch square. Lay this across the wound bed.

- 3) Place Jackson-Pratt drain in wound bed. Shorten the fenestrated drain as necessary so that the flat drain is confined to the wound bed. (The drain is never placed into the fistula tract)

- 4) Open four by four inch gauze squares. Saturate with normal saline. Fluff into wound to completely cover the drain and fill the defect to skin level.

- 5) Apply skin sealant to all skin that will be covered by transparent adhesive film dressing. Allow to dry until slick.

- 6) Cut transparent adhesive film dressing or select size to allow at least one inch of intact skin beyond wound edges. Place film dressing over packed wound. Split one end of the film dressing sheet in order to bring each "arm" around the Jackson-Pratt tubing. Crimp the edges of the film dressing around the tube.

- 7) At tube exit site, squeeze a small amount of Stomahesive Paste where film dressing meets tube to seal an air-tight closure.

- 8) Reinforce this juncture with pink tape as illustrated.

- 9) Turn your attention to the connection of the Jackson-Pratt tube to continuous suction system. A small "Christmas tree" connector is ideal to connect the end of the drain to the wall suction Solventum Corp. V. Wound Healing Techs., LLC; No IPR2025-01042

tubing. (Do not attempt to use the bulb of the Jackson-Pratt system unless you are transporting the patient for a short period of time.) If you cannot locate a small "Christmas tree" connector, you can cannibalize IV tubing to get a small plastic adapter.

- 10) Turn on continuous suction to the upper range of the low setting, approximately 60-80mmHg, and observe the wound site. The dressing should contract noticeably. If it does not, you do not have a closed system and wound drainage will override it.

Critical to the efficacy of our system is the moist gauze packing in the wound. This packing obliterates the dead space known to be an impediment to wound closure, and it is an imperative component in the suction system. We noted, as we modified our system with the first patients, that elimination of the gauze packing, the use of dry gauze packing, or gauze packing insufficient to fill the wound, all resulted in faulty and unpredictable suction efficiency.

The system is changed every three to five days, depending on the viscosity of the effluent and the surgeon's desire to examine the wound bed. The cost of the materials to establish this system and maintain it for one week is approximately \$205 at our institution. Conventional dressings, such as abdominal pads and gauze sponges, changed four to six times a day, may run as high as \$1400 per week. The amount does not include the cost of bed linen changes and nursing time. At our institution, the cost of changing a soiled bed and the patient's gown is \$4.67, including the nurse's time to make the change. No price can be placed on a patient's suffering from malodorous dressings, frequent disturbances to make the dressing changes, and the discomfort associated with denuded skin secondary to fistula drainage.

PATIENT PROFILE

From 1984 to 1986, seven patients with eight fistulae have been managed with the closed suction wound drainage system. Six of the fistulae were intestinal, one was renal, and one a lymph fistula Solventum Corp. EX1016

continued

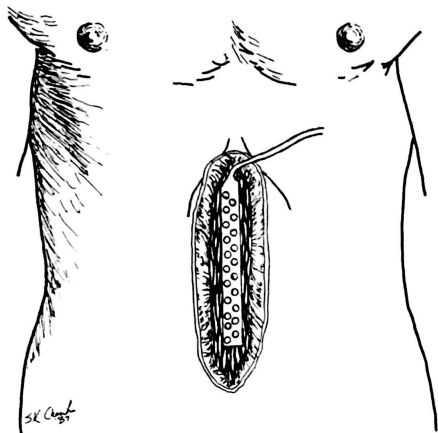


Fig. 1 A two by two inch gauze square is opened and the wound bed is protected by the gauze overlay. A Jackson-Pratt Mini-Snyder flat hemovac drain is placed in the wound bed. It is shortened as necessary.

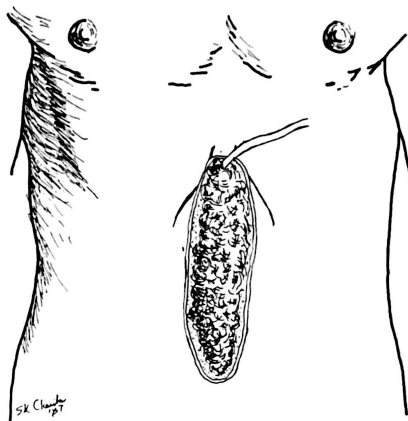


Fig. 2 The gauze overlay is tucked into the wound edge. Moist saline-soaked gauze sponges are fluffed into the wound to completely cover the drain and fill the defect to skin level.

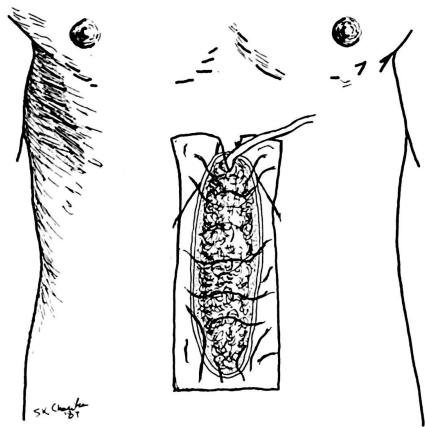


Fig. 3 A transparent adhesive film dressing is cut or a presized dressing is selected to allow at least one inch of intact skin beyond the wound edge. The dressing is split to allow the tube exit and crimped around the tube to seal.

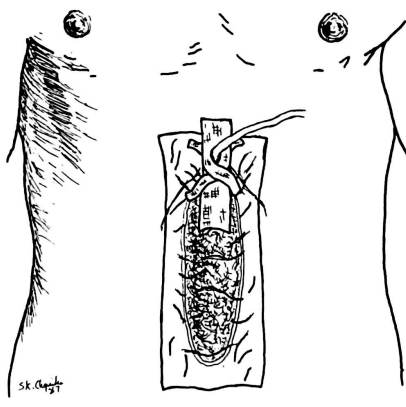


Fig. 4 After caulking the tube exit site with Stomaheasive Paste, the juncture is reinforced with a waterproof pink tape.

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located in the groin. All wounds managed with this system closed in a mean time of 16 days with a range from 8-23 days. All the fistulae were classified as small-output fistulae with a peak mean daily output of 440ml. All patients had been managed for at least one episode of intraabdominal sepsis and all patients received hyperalimentation. The mean age of the group of patients managed with this system was 57 years.

Four of seven patients in this study were discharged with closed fistulae and no recurrences. One patient was discharged from the hospital wearing a drainable colostomy pouch to collect her minimum fistula output. This fistula closed approximately one week after discharge. Two patients with enterocutaneous fistulae died as a result of congestive heart failure, but both fistulae had closed prior to death.

In the case of our renal fistula patient, use of an ostomy-type pouch would have been difficult because of the size and location of the incision. Further, it would have been impossible to estimate the amount of urine loss. In fact, it was concluded during the first three days of management with the closed suction wound system that all of the urine produced by the left kidney was draining from the flank. Once the fistula closed, the flank healed rapidly, the wound contracted, and a small scar remains.

The patient with the lymph fistula in the groin was very restless and edematous. Without our wound drainage system, collection of the effluent would have been a tedious and time-consuming challenge.

Significant in the evaluation of this wound drainage system is the comfort afforded all of these patients and the ease of their nursing care. Generally speaking, all that is required of the patient's nurse is maintenance of careful records of the output of the fistula. All patients were very sick and required a great deal of time and attention. With the closed wound drainage system, the nurse is freed to attend to the more critical elements of patient care. Usually, all that is required of the staff nurse is intermittent assessment of the system to ascertain its patency. Occasionally, if the effluent thickens, irrigations with normal saline are required.

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DISCUSSION

Continuous drainage from an abdominal wound is a common clinical problem. From the days of drainage through ostomy pouches to the current use of suction systems there has evolved a closed suction system incorporating current moist wound management principles with the benefits of the inert silicone drain to maximize wound healing.

Two basic problems in wounds complicated by draining enterocutaneous fistulae in our study are full thickness and partial thickness tissue defects. Our system contributes to wound closure by second intention. In order to have an effective closure in terms of strength and durability, wound contracture is required to allow dermal structures to approximate.¹⁰ By limiting fibroplasia, the amount of epithelial migration required to cover the granulating bed is kept at a minimum. The third tenet of wound healing affected by our system is that of inflammation, minimized by the closed suction system. The facets of wound healing that our system influences are best discussed by reviewing each component of the system as well as our wound management approach.¹¹

Eschar formation, a problem seen with dry dressing and open air techniques, is minimized with the use of moist wound healing principles reviewed by Alper.¹² The negative effects of eschar formation, as discussed by Rovee,⁹ are prevention of wound contracture, inhibition of epithelialization and enhancement of the inflammatory phase of wound healing.^{9,12,13}

Bernard was early in demonstrating the negative effects of gastrointestinal contents on living tissue.¹⁴ The effect of enterocutaneous fistulae effluent on open wounds is to stimulate fibroplasia, thus inflammation. The result is a hypertrophic granulating bed.¹⁵ The main advantage of the continuous suction is almost total elimination of the caustic effluent from the wound. The effluent removal is enhanced with the use of an overlay gauze as seen in Fig. 2. Also, constant removal of the inflammatory infiltrate, neutrophils and macrophages that are concentrated under the vapor permeable membrane, may lessen the degree of fibroplasia.¹⁶

In terms of dressing changes, the system is

changed at three to five day intervals, which is another advantage of continuous suction. By minimizing changes, granulation is again limited. This method allows for wound contracture and epithelialization during the period of fistulae drainage.

Another fine point is our use of normal saline to irrigate the wounds at the time of dressing change. Lineaweaver, et al.¹⁷ have demonstrated the inhibitory effects on fibroblast activity of agents such as 3% H₂O₂, 1% povidone-iodine, 0.25% acetic acid, and 0.5% sodium hypochloride. In experimental models, the chronic use of these agents appear to decrease the overall strength of a healing wound. We think these agents may have some role in the initial treatment of an infected and necrotic wound, but their cytotoxic effects appear to have potential for delaying wound closure.

SUMMARY

Our closed suction wound drainage system has revolutionized the management of enterocutaneous fistulae complicating ventral abdominal wounds, which have up to a 60% mortality in some studies.¹⁸ This technique eliminates the old "bridge" method described by Gross and Irving.¹⁹ It is more effective and less cumbersome. The same system has been a boon in one patient with a urinary fistula in a deep flank incision and another with a cutaneous lymph fistula. We have used it in a small group of patients; however, our initial evaluation has demonstrated that it minimizes morbidity secondary to a draining fistula, reduces time-consuming nursing requirements, and it results in significant cost reduction. It limits the degree of fibroplasia, which improves wound contracture and augments reepithelialization.

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