

# Overview of Presentations & Published Articles Relevant to Rochester Medical's

Antibacterial Products & Technology

ABSTRACTS OF PRESENTATIONS & PUBLISHED ARTICLES

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Rochester Medical Ltd  
10 Commerce Way  
Lancing, West Sussex  
BN15 8TA

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# Overview of Presentations & Published Articles Relevant to Rochester Medical's Antibacterial Products

**Materials in this section are presented in chronological order:**

J. Johnson, T. Berggren, and A. Conway. Activities of a Nitrofurazone Matrix Urinary Catheter against Catheter-Associated Uropathogens. *Antimicrobial Agents and Chemotherapy*. September 1993: Vol. 37, No. 9:2033-2036.

D. Maki, MD and R. Holcomb, PhD. A Report on the Randomized, Controlled Clinical Trail of the Nitrofurazone-Impregnated, Antibacterial, Indwelling Urinary Catheter. *White paper from Rochester Medical Corporation*. 1997.

J. Johnson, P. Delavari, and M. Azar. Activities of a Nitrofurazone-Containing Urinary Catheter and a Silver Hydrogel Catheter against Multidrug-Resistant Bacterial Characteristic of Catheter-Associated Urinary Tract Infection. *Antimicrobial Agents and Chemotherapy*. December 1999: Vol. 43, No. 12:2990-2995.

J. LeClair, MPH, et al. Effect of a Nitrofurazone-Impregnated Urinary Catheter on the Incidence of Catheter-Associated Urinary Tract Infection in Burn Patients. *Presented at the 4<sup>th</sup> Decennial International Conference on Nosocomial and Healthcare-Associated Infections*. Atlanta, GA; March 5-9, 2000.

I. Al-Habdan, et al. Assessment of Nosocomial Urinary Tract Infections in Orthopaedic Patients: A Prospective and Comparative Study Using Two Different Catheters. *International Surgery*. 2003;88:152-154.

S. Lee, et al. A Comparative Multicenter Study on the Incidence of Catheter-Associated Urinary Tract Infection Between Nitrofurazone-Coated and Silicone Catheters. *International Journal of Antimicrobial Agents*. 2004;24S:S65-S69.

J. Johnson, MD, M. Kuskowski, PhD, and T. Wilt, MD, MPH. Systematic Review: Antimicrobial Urinary Catheters to Prevent Catheter-Associated Urinary Tract Infection in Hospitalized Patients. *Annals of Internal Medicine*. 2006;144:116-126.

Stensballe, Jakob; Lippert, Freddy K; Rasmussen, Lars S; Tvede, Michael; Dahl, Benny; Looms, Dagnia; Toennesen, Else. Lower Infection Rate in Trauma Patients with Nitrofurazone-Impregnated Urinary Catheters – A Randomized, Double-Blind, Clinical Trial. *Critical Care Medicine*. 2006; Volume 34(12) Abstract Supplement, December 2006, p. A155.

# Activities of a Nitrofurazone Matrix Urinary Catheter against Catheter-Associated Uropathogens

J. Johnson<sup>1</sup>, T. Berggren<sup>1</sup>, and A. Conway<sup>2</sup>, Department of Medicine, University of Minnesota, Minneapolis, Minnesota 55455,<sup>1</sup> and Rochester Medical Corp., Stewartville, Minnesota 55976.<sup>2</sup>

## ABSTRACT

Nitrofurazone-coated urinary catheter segments inhibited 51 (75%) of 70 urinary bacterial isolates from patients with indwelling catheters. Inhibition zones correlated significantly with the nitrofurazone MIC ( $r^2 = 0.79$ ,  $P = 0.0001$ ). All strains except the *Pseudomonas* spp. were inhibited by  $\leq 64$   $\mu\text{g}$  of nitrofurazone per ml. MICs of nitrofurazone and nitrofurantoin correlated significantly ( $r^2 = 0.93$ ,  $P = 0.0001$ ).

*Antimicrobial Agents and Chemotherapy*. 1993, Vol. 37, No. 9:2033-2036.

*Funding for this study was provided by Rochester Medical Corporation. The clinical authors had complete control and responsibility for conducting the study and analyzing the data.*

# **A Report on the Randomized, Controlled Clinical Trial of the Nitrofurazone-Impregnated, Antibacterial, Indwelling Urinary Catheter**

D. Maki, M.D., University of Wisconsin-Madison and R. Holcomb, Ph.D, consultant.

## **SUMMARY**

For patients with catheters inserted for 7 days or less (91.5% of the population, median=3 days), the group receiving the Release-NF Catheter had an approximate threefold reduction in the rate of bacterial CAUTI compared to the conventional silicone catheter group (2.4% vs. 6.9% incident). The difference in actuarial survival curves for the time until the occurrence of bacterial CAUTI, between the two groups was found to be statistically significant for the first five days of use.

The antibacterial Foley catheter manufactured by Rochester Medical Corporation demonstrated that it could significantly reduce the incidence of CAUTI of bacterial origin, when compared to the use of a standard silicone catheter. The antibacterial catheter was well-tolerated by patients receiving it and no complications or attributable side-effects were observed.

*White paper from Rochester Medical Corporation. 1997.*

*Funding for this study was provided by Rochester Medical Corporation. The authors had complete control and responsibility for conducting the study and analyzing the data.*

# Activities of a Nitrofurazone-Containing Urinary Catheter and a Silver Hydrogel Catheter against Multidrug-Resistant Bacteria Characteristic of Catheter-Associated Urinary Tract Infection

J. Johnson, P. Delavari, and M. Azar; VA Medical Center and University of Minnesota, Minneapolis, Minnesota.

## ABSTRACT

The in vitro inhibitory activity of a nitrofurazone-coated urinary catheter (NFC) against 86 recently obtained susceptible and multidrug-resistant (MDR) clinical isolates of *Escherichia coli*, *Klebsiella pneumoniae*, *Citrobacter freundii*, *Staphylococcus aureus*, coagulase-negative staphylococci, and *Enterococcus faecium*, which are species implicated in catheter-associated urinary tract infection and which traditionally have been susceptible to nitrofurazone derivatives, was determined using an agar diffusion assay. In a subset of these strains, the activity of the NFC was compared with that of a silver hydrogel urinary catheter (SHC), and the durability of each catheter's inhibitory activity was assessed during serial daily transfers of catheter segments to fresh culture plates. Except for vancomycin-resistant *E. faecium*, the NFC was active against all isolates tested and showed comparable inhibition zones with susceptible and MDR strains of each species. In contrast, the SHC inhibited only certain staphylococci ( $P < 0.01$  versus the NFC), and among these strains, the SHC produced smaller inhibition zones than did the NFC ( $P < 0.01$ ). Inhibition was evident for up to 5 days with the NFC, but for only 1 day (if at all) with the SHC ( $P < 0.01$ ). These data document that, for most genera which traditionally have been susceptible to nitrofurazone derivatives, the NFC remains active against contemporary MDR isolates. They also demonstrate that the in vitro antibacterial activity of the NFC is markedly superior to that of the SHC in several respects. Thus, the NFC shows promise for clinical use in the current era of MDR bacteria.

*Antimicrobial Agents and Chemotherapy*. 1999, Vol. 43, No. 12: 2990-2995.

Funding for this study was provided by Rochester Medical Corporation. The authors had complete control and responsibility for conducting the study and analyzing the data.

# Effect of a Nitrofurazone-Impregnated Urinary Catheter on the Incidence of Catheter-Associated Urinary Tract Infection in Burn Patients

J. LeClair, MPH; K. Cysan, RN; A. Munster, MD; C. Neste, RN; and P. Murphy, MD; Johns Hopkins Bayview Medical Center and Baltimore Regional Burn Center, Baltimore, MD.

## ABSTRACT

Patients hospitalized in Burn ICU's are at higher risk of catheter-associated UTI (CAUTI) than patients in any other type of ICU, as reported by the National Nosocomial Infections Surveillance (NNIS) system. Heavy colorization of burn wound surfaces in close proximity to the catheter-urethral junction may make CAUTI in burn patients difficult to reduce using conventional methods. Because secondary bacteremia occurs in 0.5-4% of patients with CAUTI, and bacteremia significantly increases mortality in burn patients, it is imperative to minimize the incidence of CAUTI in the Burn Unit.

Surveillance in conjunction with NNIS in a regional Burn Center showed a baseline CAUTI incidence of 24.4 / 1000 catheters days. Reeducation of staff in catheter insertion and management techniques, as recommended by CDC, did not reduce the incidence of CAUTI.

In December 1998, a nitrofurazone-impregnated catheter was introduced exclusively for use in burn patients. Surveillance for CAUTI using the same NNIS definitions and methodology as in the baseline period was performed.

The device was used in thirty burn patients for periods ranging from 1-60 days for a total of 550 catheter days. Four CAUTIs occurred, for an incidence of 7.3/1000 catheter days. Three infections were due to *Candida albicans* and one to *Pseudomonas aeruginosa*.

The nitrofurazone-impregnated catheter was effective in reducing the incidence of catheter-associated urinary tract infection in a regional Burn Center. Use of these catheters may play an important role in minimizing the risk of UTI in burn patients.

Presented at the 4<sup>th</sup> Decennial International Conference on Nosocomial and Healthcare-Associated Infections. Atlanta, GA; March 5-9, 2000.

# Assessment of Nosocomial Urinary Tract Infections in Orthopaedic Patients: A Prospective and Comparative Study Using Two Different Catheters

I. Al-Habdan<sup>1</sup>, M. Sadat-Ali<sup>1</sup>, J. Ran Corea<sup>1</sup>, A. Al-Othman<sup>1</sup>, B. A. Kamal<sup>2</sup>, D. Sheena Shriyan<sup>1</sup>; Departments of <sup>1</sup>Orthopaedic Surgery and <sup>2</sup>Urology, College of Medicine, King Faisal University and King Fahd Hospital of the University, Al-Khobar, Saudi Arabia.

## ABSTRACT

Catheter-related nosocomial urinary tract infection in postoperative orthopedic and trauma patients was studied prospectively using nitrofuraxone[sic]-impregnated urinary catheters (study group) and regular silicone-coated Foley catheters. Fifty adults in each group were randomly assigned. In Group A, antibiotic-impregnated catheters were used, and in the other, nonantibiotic-impregnated urinary catheters were used (Group B). The variables studied were age, sex, type of surgery, duration of surgery, number of catheter days, days of intravenous line, and hospital days. In patients, urinary tract infection (UTI) was diagnosed by culture and the organism was isolated. The average age in the study group was 43.90 years (range, 14-95 years) compared with the control group (mean age, 42.22 years; range, 14-102 years). Catheter days in the nitrofuraxone-impregnated catheters was 7.9 days (range, 2-37 days) versus 7.2 days (range, 2-30 days). There were six infections ( $P = 0.028$ ) in the control group compared with the study group. The length of operation was similar in each group. Our study indicates that nitrofuraxone-impregnated catheters have the potential to reduce nosocomial catheter-related UTIs in postoperative orthopedic and trauma patients.

*International Surgery*; 2003;88:152-154.

**NOTE:** Rochester Medical notes this abstract and the full-text article mistakenly refer to nitrofuraxone [sic] as an antibiotic. Nitrofurazone is a non-systemic antimicrobial.

# A Comparative Multicenter Study on the Incidence of Catheter-Associated Urinary Tract Infection Between Nitrofurazone-Coated and Silicone Catheters

S. Lee<sup>a</sup>, S.W. Kim<sup>a</sup>, Y. Cho<sup>a</sup>, W. Shin<sup>b</sup>, S.E. Lee<sup>c</sup>, C. Kim<sup>d</sup>, S.J. Hong<sup>e</sup>, B.H. Chung<sup>e</sup>, J.J. Kim<sup>f</sup>, M.S. Yoon<sup>a</sup>, Department of Urology: St. Mary's Hospital, Catholic University, 62 Yeouido-dong, Yeongdeungpo-gu, Seoul 150-713, South Korea<sup>a</sup>; Catholic University, Seoul, South Korea<sup>b</sup>; Seoul National University, Seoul, South Korea<sup>c</sup>; Ulsan University, Seoul, South Korea<sup>d</sup>; Yonsei University, Seoul, South Korea<sup>e</sup>; Amore Pacific Corporation R&D Center, Yongin, South Korea<sup>f</sup>.

## ABSTRACT

The efficacy of nitrofurazone-coated urinary catheter in inhibitory activity of catheter-associated urinary tract infection (CAUTI) was evaluated. The incidence rate and onset of CAUTI after catheterization of standard silicone urinary catheters and nitrofurazone-coated catheters was compared. There was no statistical significance between the two groups in the incidence rate of CAUTI. However, in patients who had indwelling urinary catheters for 5-7 days, the incidence rate of CAUTI was significantly lower in the experimental group. Logistic regression analysis showed that the two variables including age and period of insertion, affected the incidence rate of CAUTI significantly. Nitrofurazone-coated catheters can be useful for inhibition of CAUTI in patients who have indwelling urinary catheter for 5-7 days and in old-age patients.

*International Journal of Antimicrobial Agents*; 2004;24S:S65-S69.

# Systematic Review: Antimicrobial Urinary Catheters to Prevent Catheter-Associated Urinary Tract Infection in Hospitalized Patients

J. Johnson, MD; M. Kuskowski, PhD; and T. Wilt, MD, MPH; Veterans Affairs Medical Center, Minneapolis, Minnesota.

## ABSTRACT

*Background:* The efficacy of antimicrobial urinary catheters in hospitalized patients is poorly defined. *Purpose:* To assess currently marketed antimicrobial urinary catheters from preventing catheter-associated urinary tract infection (UTI).

*Data Sources:* Electronic databases, conference proceedings, bibliographies, trialists, and catheter manufacturers (search dates, 1966 to June 2005). *Study Selection:* Randomized and quasi-randomized trials of nitrofurazone-coated or silver alloy-coated antimicrobial urinary catheter use for less than 30 days; no language restriction.

*Data Extraction:* Study design, study sample, inclusion and exclusion criteria, allocation, blinding, UTI definition, ascertainment methods, and proportion developing symptomatic UTI (primary end point) or bacteriuria (secondary end point) were extracted by using a structured data collection instrument.

*Data Synthesis:* Twelve qualifying trials (13 392 total participants or catheters) were identified. They compared nitrofurazone-coated silicone ( $n = 3$ ) or silver-coated latex ( $n = 9$ ) catheters were silicone or latex catheters. No study addressed symptomatic UTI. All trials suggested protection against bacteriuria with test catheter use. However, effect size varied considerably and postrandomization exclusions were very common. Effect size was greatest in trials of nitrofurazone-coated catheters (all post-1995) and in pre-1995 silver alloy-coated catheter trials and was smallest in post-1995 silver alloy-coated catheter trials. Control group bacteriuria rate, control catheter type (latex vs. silicone), and patient sample (urology vs. other) also predicted effect size. Few studies addressed secondary bloodstream infection, mortality, costs, or microbial resistance. Short-term adverse effects were minimal.

*Limitations:* The study was limited by the number, size, and quality of studies and by lack of the following: intention-to-treat analyses, data on clinical end points, and trials comparing nitrofurazone-coated with silver alloy-coated catheters.

*Conclusions:* According to fair-quality evidence, antimicrobial urinary catheters can prevent bacteriuria in hospitalized patients during short-term catheterization, depending on antimicrobial coating and several other variables. Older data probably lack current relevance. Cost implications and effect on infectious complications remain undefined.

*Annals of Internal Medicine.* 2006;144:116-126.

*Funding for this study was provided by Rochester Medical Corporation. The authors had complete control and responsibility for conducting the study and analyzing the data.*

# Lower Infection Rate in Trauma Patients with Nitrofurazone-Impregnated Urinary Catheters – A Randomized, Double-Blind, Clinical Trial

Stensballe, Jakob; Lippert, Freddy K; Rasmussen, Lars S; Tvede, Michael; Dahl, Benny; Looms, Dagnia; Toennesen, Else

## SUMMARY

*Introduction:* The purpose was to investigate whether nitrofurazone (NF) impregnated urinary catheters could reduce the incidence of catheter-associated urinary tract infection (CAUTI) in trauma patients, compared to standard silicone catheters.

*Hypothesis: Methods:* From July 2003 to August 2005, adults ( $\geq 18$ y) needing a urinary catheter when admitted were randomized to either a NF-impregnated (Releen NF, Coloplast A/S) or a silicone (Simpla All Silicone, Coloplast A/S) catheter. Exclusion criteria were: HIV, pregnancy, steroid treatment, and unattainable informed consent. The calculated sample size was 212 (80% power to detect a 65% reduction in CAUTI; significance  $p < 0.05$ ; expected dropout 12). The predefined criterion for inclusion in the analysis was a minimum follow-up of 24 h. The primary outcome was CAUTI defined as  $\geq 10 \times 10^3$  CFU/mL of at least one bacteria or fungus. Daily urine cultures were performed until catheter removal. Patients and outcome assessor were blinded. The local ethical committee approved the study.

*Results:* Urine samples were available for 77/106 patients in each group after 24 h. Lack of 24-h follow-up was mainly (39/58) due to death caused by trauma or catheter removal. The occurrence of CAUTI was 19/77 (24.7%) in the silicone and 7/77 (9.1%) in the NF group ( $p = 0.0098$ , Chi<sup>2</sup> test). The incidence of CAUTI per 1000 catheter-days was 38.7 in the silicone and 13.8 in the NF group. Furthermore, the onset time of CAUTI was significantly delayed in the NF group ( $p = 0.01$ , logrank test).

*Conclusions:* The study found a significantly reduced incidence of CAUTI in adult trauma patients when NF catheters were used, as compared to patients who had standard silicone catheters.

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## Antibacterial Technology

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G. Marion-Landais, M.D , et al. Non-Absorption of Furazolidone from the Vagina in Women. *Current Therapeutic Research*. 1975; Vol.18, No. 3:510-512.

G. Marion-Landais, M.D , et al. Non-Absorption of Nitrofurazone from the Urethra in Men. *Current Therapeutic Research*. 1976; Vol.19, No. 5:550-553.

G. Hooper, BSc and J. Corvarrubias, BSc. Clinical Use and Efficacy of Furacin: A Historical Perspective. *The Journal of International Medicine Research*. 1983;11:289-293.

R. Fryar. CAUTIs: What Can We Do? *Managing Infection Control*. August 2001;32-36.

D. Guay, Pharm.D. An Update on the Role of Nitrofurans in the Management of Urinary Tract Infections. *Drugs* 2001. 61 (3):353-364.

# Non-Absorption of Furazolidone from the Vagina in Women

G. Marion-Landais, M.D., J.P. Heotis, Ph.D., R. Herrett, M.S., and J. Diaz, B.S., Medical and Research Development Departments, Eaton Laboratories, Division of Morton-Norwich Products, Inc., Norwich, New York.

## ABSTRACT

No furazolidone could be detected in the blood, plasma, or urine within 3 to 12 hours (blood and plasma) or 24 hours (urine) after 5 or 20 mg. of furazolidone in suppositories was administered intravaginally to healthy women, 6 to each dose. The analytic method detects furazolidone at concentrations as low as 2 parts per billion (2 ng./ml.). We conclude that little or no intact furazolidone was absorbed into body fluids across the vaginal mucosa.

Current Therapeutic Research. Vol. 18, No. 3, September 1975. 510-512.

# **Non-Absorption of Nitrofurazone from the Urethra in Men**

G. Marion-Landais, M.D., J.P. Heotis, Ph.D., J. Mertz, Ph.D., J. Diaz, B.S., and D. Van Hart, B.A.  
Eaton Laboratories Division, Morton-Norwich Products, Inc., Norwich, New York.

## **ABSTRACT**

Suppositories, each containing nitrofurazone 3 mg., were inserted into the urethras of 6 healthy men. During the next 12 hours nitrofurazone could not be detected in the blood, by a programmed multiple development (PMD) tlc method capable of measuring the drug at levels down to 2 ng./ml. (2ppg). Transient discomfort was the only observed side effect.

Current Therapeutic Research. Vol. 19, No. 5, May 1976. 550-553.

# Clinical Use and Efficacy of Furacin: A Historical Perspective

G. Hooper, BSc, MBChB, DipPharmMed RCP (UK) and J. Covarrubias, BSc, MD, BC, Pediatrician; Norwich Eaton Pharmaceuticals, Inc., Norwich, New York 13815, USA.

## SUMMARY

This paper discusses the use of nitrofurazone in the treatment, or prophylaxis, of wound infection, various pyodermas and second and third degree burns, as well as its prophylactic use in skin grafting and donor sites. The literature is reviewed over three decades.

The literature reviewed here reports the use of nitrofurazone in the treatment of wounds, dermatologic conditions and burns for over 30 years.

Nitrofurazone has enjoyed such use because of its bactericidal properties and because of its effectiveness against a wide range of Gram-positive and Gram-negative organisms. Nitrofurazone continues to be effective, in spite of its long history of use, since bacterial resistance and cross resistance have been negligible. It is important to note that nitrofurazone is used topically and therefore does not interfere with concomitant systemic therapy. Moreover, nitrofurazone does not cause pain on application. Since it is not cytotoxic and does not cause maceration, it does not impede healing. Nitrofurazone's ability to penetrate burn eschar and to remain stable and effective in the presence of blood, pus and serum are major advantages contributing to its clinical importance.

*The Journal of International Medicine Research*. 1983;11:289-293.

# **CAUTIs: What Can We Do?**

R. Fryar; Vice President of Research and Development, Rochester Medical Corporation.

## **SUMMARY**

Catheter-associated urinary tract infection (CAUTI) is the most common nosocomial infection. Each year more than a million patients in acute care hospitals and extended-care facilities acquire such an infection. The rate of infection is high and the cost is staggering. New urinary catheters show promise to reduce both the rate and the cost of these infections.

*Managing Infection Control*; August 2001:32-36.

# An Update on the Role of Nitrofurans in the Management of Urinary Tract Infections

D. Guay, Pharm.D., FASCP, FCCP, CGP, FCP, Professor; University of Minnesota, Institute for the Study of Geriatric Pharmacotherapy, and College of Pharmacy, Minneapolis, Minnesota, USA

## ABSTRACT

There have been few recent reviews of the nitrofurans in the literature, and none include recently available data on the use of nitrofurazone (nitrofurazone) in the prevention of catheter-associated urinary tract infection (CAUTI). Nitrofurazone and nitrofurantoin are the only nitrofurans that have become established in clinical use in the 20<sup>th</sup> century. These 2 nitrofurans have remained clinically useful against a wide-spectrum of Gram-positive and Gram-negative bacteria, including many strains of common urinary tract pathogens. Today, the primary use of nitrofurantoin is as an oral antibacterial treatment for genitourinary infections. Nitrofurazone is primarily used as a topical antibacterial agent in burns and skin grafts and recently was approved for the prophylaxis of CAUTI. The recent development of a nitrofurazone-impregnated catheter as a novel modality in the prevention of CAUTI reflects a renewed interest in the effectiveness of nitrofurans. In an era when concern about bacterial resistance to many anti-infective agents is growing, the nitrofurans have continued to be active against organisms that have developed resistance to antibacterials. The presence of multiple mechanisms of action for the nitrofurans might be expected to reduce the ability of bacteria to develop resistance. Considering that an emergence of resistance to the nitrofurans has not appreciably occurred after several decades of clinical use, the nitrofurans may be unique among common antibacterial agents in this regard.

*Drugs 2001; 61 (3):353-364.*

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