

# Multicenter Infection Surveillance Study Comparing Two Types of Postoperative Pain Management, Surgical Site Using ON-Q® SilverSoaker™ and Local Anesthetics vs. Systemic Narcotics Following Colorectal Procedures

**Presented at: 47th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy. Chicago, IL 9/2007**

*Singh J<sup>a</sup>, Hum M<sup>a</sup>, Cohen S<sup>b</sup>, Liberman H<sup>b</sup>, Thorson A<sup>c</sup>, Dine A<sup>d</sup>, and the MISS Study group*

## **Affiliations**

<sup>a</sup> Piedmont Colorectal Associates, Atlanta, USA

<sup>b</sup> Atlanta Colon and Rectal Surgeons, Atlanta, USA

<sup>c</sup> Creighton University School of Medicine and the University of Nebraska College of Medicine, Omaha, USA

<sup>d</sup> I-Flow Corporation, Lake Forest, USA

## **BACKGROUND**

Surgical site infections (SSI) are the most common nosocomial infection in surgical patients. The consequences of these infections may result in increased pain, increased hospital length of stay (LOS), increased costs to patient and facility, and potentially sepsis and mortality. The mean cost of an SSI has been estimated as \$15,646<sup>1</sup> and each infection may require more outpatient visits, ER visits, radiology services, readmissions and home health aid services. SSI's may result in \$1-\$10 BILLION in direct and indirect medical expenses each year.<sup>2</sup> SSI patients are more than twice as likely to die, 60% more likely to be admitted to an ICU and more than 5 times more likely to be readmitted to the hospital.<sup>3</sup> Opioids are the current standard of care for postoperative pain management after colorectal surgery. Both unrelieved pain and opioid usage have been implicated as additional risk factors for SSI causing peripheral vasoconstriction and an impaired immune response to bacterial invasion. A continuous infusion of local anesthetic to the surgical site has been shown to significantly reduce both pain and opioid usage.

## **METHODS**

Following IRB approval, a prospective, multicenter, randomized, open, controlled, surveillance study of surgical infection rates in elective colorectal surgery was performed. Patients were randomized to receive either continuous, surgical site infusion of local anesthetic via the ON-Q® PainBuster with SilverSoaker™ (study group) or traditional narcotic pain management via PCA or epidural (control group) in order to compare the SSI rate associated with each modality. Both groups had available institutional standard of care for breakthrough pain. The presence or absence of SSI was determined 30 days postoperative. A secondary outcome measure was hospital length of stay.

## **RESULTS**

In total, 289 patients were recruited for the study: 152 in the study group and 137 in the control group. The incidence of SSI was found to be significantly less in the continuous surgical site infusion group compared to the control group (6.6% versus 14.6%,  $p = 0.033$ ). The LOS was lower in the study group compared to the control group (6.1 days versus 8.4 days,  $p = 0.0003$ ).

Variable	ON-Q SilverSoaker	Control	Total	P-value
<b>N=</b>	<b>152</b>	<b>137</b>	<b>289</b>	
<b>Infection</b>	<b>10 (6.6%)</b>	<b>20 (14.6%)</b>	<b>30 (10.4%)</b>	<b>0.033</b>
Superficial	6	11		
Deep	4	7		
Organ Space	0	2		

Infection by Procedure	ON-Q SilverSoaker %	Control %	P-value
<b>Overall</b>	<b>6.6%</b>	<b>14.6%</b>	<b>0.033</b>
Open	9.8%	12.5%	
Laparoscopic + Hand Assist	3.7%	17.5%	0.006
Laparoscopic	0	16.7%	0.02
Hand Assist	5.7%	18.5%	0.006

Length of Stay All Patients (days)	ON-Q SilverSoaker	Control	P-value
<b>All</b>	<b>6.1</b>	<b>8.4</b>	<b>0.0003</b>
Open	7.4	9.7	0.018
Laparoscopic + Hand Assist	4.9	6.5	0.025
Laparoscopic	4.9	6.2	
Hand Assist	4.9	6.8	

Length of Stay with Infection (days)	ON-Q SilverSoaker	Control
<b>All</b>	<b>7.8</b>	<b>12.8</b>
Open	8.7	15.0
Laparoscopic + Hand Assist	5.7	10.7
Laparoscopic	n/a	8.4
Hand Assist	5.7	13.0

Regression Analysis of Infection\*

**UNADJUSTED ANALYSIS**

	<b>Odds Ratio</b>	<b>95% CI LB</b>	<b>95% CI UB</b>	<b>p value<sup>1</sup></b>
Control verses ON-Q	2.43	1.09	5.39	0.029

**MULTIVARIABLE ADJUSTED ANALYSIS**

	<b>Odds Ratio</b>	<b>95% CI LB</b>	<b>95% CI UB</b>	<b>p value<sup>1</sup></b>
Control verses ON-Q	2.79	1.16	6.73	0.022
Diabetes	3.73	1.41	9.89	0.008
Procedure > 120 min	5.04	1.94	13.08	0.001
Open procedure	1.19	0.51	2.80	0.69

*\*Logistic analysis with surgical site infection (SSI). Results indicate that the odds of experiencing an SSI are 2.43 times larger (95% CI 1.09 to 5.39, p=0.029) among control patients compared to those receiving ON-Q. After multivariable adjustment for the most important factors independently associated with SSI risk (diabetes and procedure duration) or in which there were significant group differences (open procedure), the estimated odds ratio for surgical site infection increased to 2.79 (95% CI 1.16 to 6.73).*

Regression Analysis of Length of Stay\*\*

**UNADJUSTED ANALYSIS**

	<b>Ratio of Expected LOS</b>	<b>95% CI LB</b>	<b>95% CI UB</b>	<b>p value<sup>1</sup></b>
Control verses ON-Q	1.31	1.16	1.49	<0.0001

*\*\*Results indicate that the average hospital length of among patients without ON-Q is 1.31 times larger (95% CI 1.16 to 1.49, p<0.0001) than among patients receiving ON-Q*

## CONCLUSIONS

Continuous, surgical site, local anesthetic infusion via the ON-Q SilverSoaker appears to significantly reduce the risk of SSI and length of stay in patients undergoing elective colorectal surgery. Further research is necessary to gain greater understanding into the mechanisms associated with these results including defining the opioid effects on the immune and vascular response to SSIs and the role of improved pain management with reduced opioid consumption for lowering the risk of surgical site infections.

<sup>1</sup> Stone PW, Larson E, Kavar LN. A systematic audit of economic evidence linking nosocomial infections and infection control interventions: 1990-2000. *Am J Infect Control* 2002;30:145-52.

<sup>2</sup> Perencevich EN et al. Health and economic impact of surgical site infections diagnosed after hospital discharge. *Emerg Infect Dis.* 2003 Feb;9(2):196-203.

<sup>3</sup> Kirkland KB, Briggs JP, Trivette SL, Wilkinson WE, Sexton DJ. The impact of surgical-site infections in the 1990s: attributable mortality, excess length of hospitalization, and extra costs. *Infect Control Hosp Epidemiol.* 1999;20:725-730.

**ON-Q**<sup>®</sup> PainBuster<sup>®</sup>  
Redefining Recovery™

**ON-Q**<sup>®</sup> SilverSoaker™  
Redefining Recovery™



**Rx only.**

I-Flow, ON-Q, PainBuster and AskYourSurgeon are registered trademarks of I-Flow Corporation.  
SilverSoaker and Redefining Recovery are trademarks of I-Flow Corporation.



**800.448.3569 or 949.206.2700**  
20202 Windrow Drive | Lake Forest | California 92630

[www.iflo.com](http://www.iflo.com)  
[www.AskYourSurgeon.com](http://www.AskYourSurgeon.com)