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Clinical Literature Summary

ACCURYN® MONITORING SYSTEM

MKT-06-101399 Rev A

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Introduction: Urine Output

Timely, accurate vital signs monitoring can mean the difference between life and death for critically ill patients. But current techniques for gathering urine output data can be complicated, inaccurate and may increase the risk of urinary tract infection.1 Causes of inaccurate readings could be urine retention and urine trapped in the drain line.

The Accuryn Monitoring System transforms the traditional indwelling urinary catheter (IUC) into a next-generation diagnostic tool for precise, real-time measurement of urine output (UO) and core body temperature to help guide care.

Intensive monitoring of urine output is associated with increased detection of acute kidney injury and improved outcomes.

Jin K, Murugan R, SileanuFE, et al. Intensive Monitoring of Urine Output Is Associated With Increased Detection of Acute Kidney Injury and Improved Outcomes. CHEST (2017), doi:10.1016/j.chest.2017.05.011.

Background
Urine Output (UO) is a vital sign for critically ill patients, but standards for monitoring and reporting vary widely between ICUs. Careful monitoring of UO could lead to earlier recognition of acute kidney injury (AKI) and better fluid management. The investigators sought to determine if the intensity of UO monitoring is associated with outcomes in patients with and those without AKI.

Method
This was a retrospective cohort study including 15,724 adults admitted to ICUs from 2000 to
2008. Intensive UO monitoring was defined as hourly recordings and no gaps > 3 hours for the first 48 hours after ICU admission.

Results
»» Intensive monitoring of Urine Output was conducted in 4,049 patients (26%)
»» Authors found significantly higher rates of AKI in these patients
»» After adjustment for age and severity of illness, intensive Urine Output monitoring was associated with improved survival but only among patients experiencing AKI
»» With or without AKI, patients with intensive monitoring also had less cumulative fluid volume
(2.98 L vs 3.78 L) and less fluid overload (2.49% vs 5.68%) over the first 72 hours of ICU stay

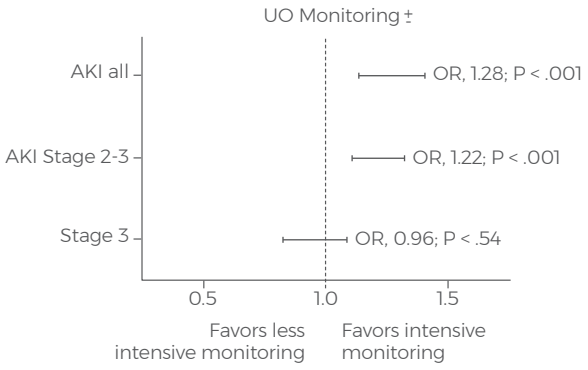
Conclusion
In this large ICU population study the Authors demonstrated:

»» Improved detection of AKI

»» Reduced 30-day mortality in patients experiencing AKI

»» Decrease in fluid overload for all patients

By comparison, intensive monitoring of Serum Creatinine showed no effect on 30-day mortality associated with AKI.



Intensive urine output monitoring is associated with increased detection of moderate to severe AKI.

Traditional Foley drainage systems—Do they drain the bladder?

Garcia MM, Gulati S, Liepmann D, Stackhouse GB, Greene K, Stoller ML.
Traditional Foley drainage systems—do they drain the bladder? J Urol 2007;177:203–7;

Background
It is assumed that Foley catheters drain the bladder completely, but Foley catheter system drainage characteristics are poorly understood.

Method
Bedside bladder ultrasound volumetric studies were performed on 150 hospitalized patients (75 ICU, 75 ward) with indwelling Foley catheters who participated in the study. Bladder volumetrics were performed between 07:00 and 08:00, before first ambulation after sleep. Volumetrics were performed independent of scheduled drainage tubing manipulation. If residual urine was identified the drainage tubing was manipulated to facilitate drainage.

Results
Bladder Ultrasound Volumetrics

»» Mean residual volume in patients on the ward (38 men, 37 women) and in the ICU (39 men, 36women) was 136 ml (range 22 to 647) and 96 ml (range 4 to 290), respectively.

»» A residual volume of at least 25 ml was documented in ward (48%) and ICU (72%) subjects. In nearly all cases the catheter drainage tubing was milked to induce outflow of residual urine to confirm ultrasound findings.

»» A minimum of 50% of the residual volume recorded by ultrasound volumetrics was confirmed.

Conclusion
Contrary to long held assumptions, traditional Foley catheter drainage does not consistently or completely evacuate the bladder. The associated residual urine likely contributes to nosocomial urinary tract infections and a myriad of other problems that stem from occult incomplete catheter drainage.

Residual urine volumes of patients in ward and ICU

Ward measured urine (cc):	No. Pts
Less than 25	39
26-50	6
51-75	4
76-100	12
Greater than 100	14
ICU measured urine (cc):	
Less than 25	21
26-50	20
51-75	13
76-100	5
Greater than 100	16

Compared to the Bard Criticore urine monitor the Accuryn critical care monitoring system with automated drainage tube clearance reduces the airlocks and periods of false oliguria.

Output Measurements due to Urinary Retention in Catheterized Patients in the Burn ICU. J Burn CareRes. 2017 Jan/Feb;38(1).

Background
Urine Output (UO) is the primary physiological sign used to guide fluid therapy during burn resuscitation. Electronic UO monitors can cause inaccurate UO measurements due to the formation of airlocks causing urine retention in the tubing and bladder.

Method
In a multi-center study in burn intensive care units, UO was measured in patients who were randomized into two separate groups:

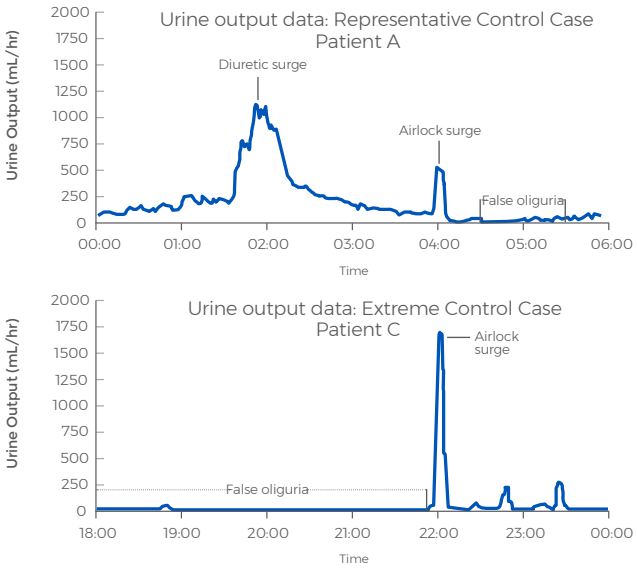
»» A control group using the Critcore electronic urine monitors (Bard Medical) with a standard Foley catheter system (Bard Medical).

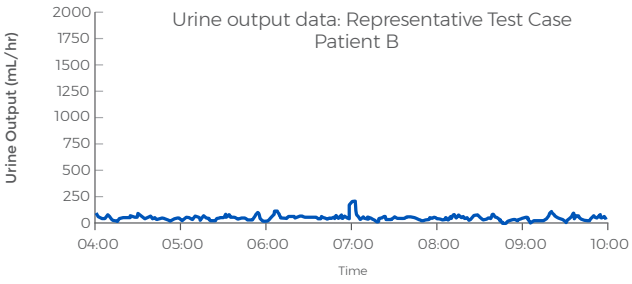
»» A test group using the Accuryn (Potrero Medical, San Francisco, CA) with automated airlock clearing drainage tubing system.

Results
A total of 18 patients were enrolled in the study with 1 patient in each group participating in the study twice. Performance data was thus generated for 10 patients in the control group and 10 patients in the test group.

»» In the control group, 5 of 10 (50%) patients experienced airlocks which impeded drainage line flow. Six associated periods of false oliguria were also noted in the control patients.

»» Airlock surge volumes ranged from 50 to 329 ml, and false oliguria duration ranged from 31.90 to 190.2 minutes.
»» In the test group, 0 of 10 (0%) patients had drainage line impediments from airlocks ($P < .01$), and therefore no periods of false oliguria were seen.





The control group used Criticore electronic urine monitors (Bard Medical) with a standard Foley catheter system (Bard Medical), the test group used the Accuryn (Potrero Medical, San Francisco, CA) with automated airlock clearing drainage tubing system.

Introduction:
Intra-Abdominal Pressure (IAP)

Intra-abdominal hypertension (IAH) has a prevalence of at least 50% in the critically ill population and has been identified as an independent risk factor for death. Still, many members of the critical care team are unaware of the consequences of untreated IAH and therefore do not regularly assess for intra-abdominal pressure (IAP).

This lack of awareness is often compounded by a lack of confidence in traditional IAP measurement methods. Traditional methods for measuring IAP often involve complex setups, increasing the risk for error. Some techniques even require opening the closed drainage system—putting patients at an increased risk for a catheter-associated urinary tract infection (CAUTI).

Nevertheless, there is a strong case for regular measurement of IAP as part of an evidence based protocol. These measurements can be used to better guide patient care to help reduce occurrences and complications of intra-abdominal hypertension and abdominal compartment syndrome.

The diagnosis and management of IAH and Abdominal Compartment Syndrome (ACS) have changed significantly over time with an improved understanding of the pathophysiology and appropriate treatment of these disease processes. Serial intra-abdominal pressure (IAP) measurements, nonoperative pressure-reducing interventions, and early abdominal decompression for refractory intra-abdominal hypertension or abdominal compartment syndrome are all key elements of this developing strategy.

Together with these protocols, intra-abdominal pressure readings can empower clinicians to improve clinical outcomes and save patient lives.

WSACS Recommendations 2013

WSACS* is the World Society of the Abdominal Compartment Syndrome. This group of established thought leaders in intra-abdominal pressure and its related pathologies puts forth guidelines on when to measure intra-abdominal pressure and how to treat the condition based on the current body of research.

Based on these guidelines:

Definitive risk factors exist for intra-abdominal hypertension and abdominal compartment syndrome. Facilities should monitor IAP on all emergency intensive care unit admissions and 'at risk' patients.1

Physical exam is an unreliable indicator of IAH/ACS because clinical signs show up late in clinical course (once ACS occurs).2

Instead, protocolized monitoring and management of IAP is recommended.3

For more information on the World Society of the Abdominal Compartment Syndrome's recommendations, including patient risk factors, go to:
http://www.wsacs.org/foam-resources/education/guidelines-slide-set.html

To reference the World Society's algorithms on the diagnosis and management of Intra-abdominal Hyper-tension and Abdominal Compartment Syndrome, go to: **http://www.wsacs.org/foam-resources/education/algorithms.html**

Following these guidelines can lead to earlier recognition of IAH, early clinical intervention, and reduced organ failure, mortality, and cost.4

*In June 2017, WSACS changed their name to WSACS—The Abdominal Compartment Society to reflect their focus on the health of the entire abdominal compartment and their focus on intra-abdominal hypertension, not just abdominal compartment syndrome.

1.Malbrain ML, Cheatham ML, Kirkpatrick A, et al. Results from the International Conference of Experts on Intra-abdominal Hypertension and Abdominal Compartment Syndrome. I. Definitions. Intensive Care Med. 2006;32:1722–1732.RM-002868. 2. Gallagher JJ, AACN Adv Crit Care. 2010 Apr-Jun;21(2):205-19.
Intra-abdominal hypertension: detecting and managing a lethal complication of critical illness. 3. "WSACS endorsement." WSACS, World Society of the Abdominal Compartment Syndrome, www.wsacs.org/. 4. 2. Cheatham ML, Safcsak K, Sugrue M. Long-term implications of intra-abdominal hypertension and abdominal compartment syndrome: physical, mental, and financial. Am Surg. 2011 Jul;77 Suppl 1:S78-82.

Intra-abdominal hypertension affects approximately 50% of critically ill patients and is an independent risk factor of early death

Blaser AR, Regli A, Keulenaer B et al. Incidence, Risk Factors, and Outcomes of Intra-abdominal Hypertension in Critically Ill Patients—A Prospective Multicenter Study (IROI Study). Crit Care Med. 2019; Advance Online Publication. DOI: 10.1097/CCM.0000000000003623.

Background
Research suggests that intra-abdominal hypertension (IAH) may lead to organ dysfunction and abdominal compartment syndrome, but few studies have systematically examined the role of IAH as an independent risk factor of mortality. This large, prospective cohort study aimed to conclude if IAH has an effect on patient mortality.

Method
This study included 491 adult patients with urinary catheters from 15 intensive care units worldwide. Intra-abdominal pressure was measured at minimum every eight hours, and patients with intra-abdominal pressure greater than 12 mmHg were defined as having IAH. Patients were followed for at least 90 days to measure the rate of mortality.

Results
Prevalence of IAH:

»» 49% of patients experienced IAH at some point during the observational period

Prevalence and severity of intra-abdominal hypertension by grade (as a percent of total patients with IAH)			
Grade I	Grade II	Grade III	Grade IV
47.5%	36.6%	11.7%	4.2%

Risk factors for IAH:

»» Overweight (BMI > 27 Kg/m2)

»» Mechanical ventilation (PEEP > 7 cmH2O)

»» Severe illness (APACHE II Score > 18) Effect of IAH on length of stay (LOS):

»» IAH associated with longer LOS in the ICU and total hospital stay Effect of IAH on mortality:

»» Development of IAH was an independent predictor of 28- and 90-day mortality

»» The severity of IAH shared a direct relationship with the patient's likelihood of dying within 90 days

Conclusion
Intra-abdominal hypertension is common in critically ill patients, and is an independent risk factor of 28- and 90-day mortality. Furthermore, as intra-abdominal pressure increases, the patient is more likely to experience early death. Careful monitoring of intra-abdominal pressure may help identify at-risk patients who require medical intervention.

Comprehensive IAH/ACS management strategies that include IAP monitoring deliver improved outcomes and results.

Cheatham ML, Safcsak K. Is the evolving management of intra-abdominal hypertension and abdominal compartment syndrome improving survival?. Crit Care Med. 2010Feb;38(2):402-7.

Background
In the past intra-abdominal hypertension (IAH) and abdominal compartment syndrome (ACS) have been poorly understood diseases of the traumatically injured patient. Over time, IAH and ACS have been recognized as significant causes of morbidity and mortality among all types of critically ill patients. In this evolving strategy, serial measurement of intra-abdominal pressure (IAP) has become key in identifying the presence of elevated IAP, an independent predictor of mortality.

Method
This was a prospective observational study of 478 patients to see how an evidence based approach could change survivability amongst patients with IAH/ACS severe enough to require an open abdomen.

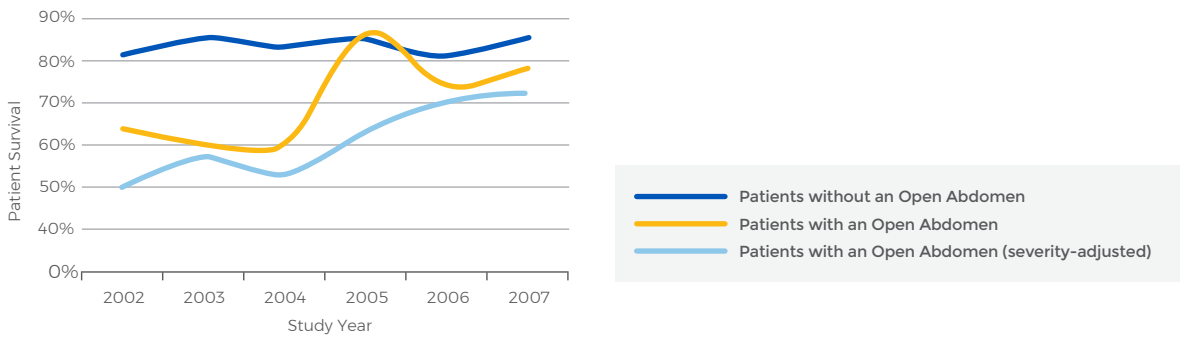
Results
»» Implementation of a management algorithm in patients with IAH and ACS can improve both clinical outcomes and reduce resource utilization.

»» Significant improvement in patient survival to hospital discharge from 50% in 2002 to 72% in 2007 (p=<.015).

»» Use of the open abdomen decreased by >50% since the implementation of evidence based guidelines to measure and treat intra-abdominal pressure.

Outcome	2002	2003	2004	2005	2006	2007
Mean days to abdominal closure	20 ± 14	17 ± 19	17 ± 14	16 ± 17	13 ± 16	10 ± 10 [b]
Median days to abdominal closure	20	8	13	12	6[a]	6[a]
Survival to hospital discharge, %	50	57	52	63	69	72[a]

All other comparisons are statistically significant. [a]p< .05;[b]p< .01.



Appropriate management of the patient with IAH/ACS is associated with both significantly improved patient survival and decreased resource use through adoption of a multidisciplinary IAH/ACS management protocol.

Cheatham ML, Safcsak K, Sugrue M. Long-term implications of intra-abdominal hypertensionand abdominal compartment syndrome: Physical, mental, and financial. Am Surg. 2011;77 (Suppl 1):S78–82.

Background

»» Patient survival after the development of intra-abdominal hypertension (IAH) and abdominal compartment syndrome (ACS) has improved significantly over the past two decades through improved diagnosis and multidisciplinary management.

»» In 2006 and 2007, the World Society of the Abdominal Compartment Syndrome (WSACS) published both evidence-based medicine definitions and recommendations as well as treatment algorithms for the diagnosis, resuscitation, and surgical management of patients with IAH/ACS, which includes IAP as a diagnostic measurement.

Method

Studies from institutions that adopted the use of a multidisciplinary IAH/ACS management protocol were reviewed to show the outcomes achieved.

Results

»» Increased awareness of the etiology, prevalence, and patient groups at high risk for IAH/ACS is essential.

»» Earlier recognition and appropriate intervention in patients at risk for IAH/ACS, as demonstrated in the studies reviewed, will significantly reduce a hospital's resource use while at the same time improve patient survival.

»» Published mortality rates approaching 100 percent have been replaced by mortality rates of 20 to 50 percent depending on age and mechanism of injury.

»» These improvements are easily achievable by virtually any hospital through adoption of a multidisciplinary IAH/ACS management protocol.

	Primary	PAC	Mesh	Skin Only	STSG
Intensive care unit LOS (days)	11 ± 12	21 ± 14	24 ± 14	23 ± 14	32 ± 19
Hospital LOS (days)	25 ± 21	42 ± 21	44 ± 20	49 ± 22	70 ± 39
Mechanical ventilation (days)	9 ± 10	19 ± 12	23 ± 16	20 ± 16	31 ± 23
Definitive closure (days)	5 ± 4	19 ± 9	16 ± 11	21 ± 14	39 ± 23*
Hospital charges ($1000)	$227 ± 206	$378 ± 209	$491 ± 279	$459 ± 274	$598 ± 335*

* P < 0.0001. PAC, progressive abdominal closure; STSG, split-thickness, skin graft; LOS, length of stay.