

A NEW APPROACH TO URINARY DRAINAGE
ABDOMINAL LEVEL COLLECTION

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Abstract: In a study with forty-one patients, we assessed the efficacy of a new urinary collection system: one in which the reservoir, or bag, is worn on the abdomen.

Traditionally it has been suggested that any collection device should be maintained below the bladder. The results of our evaluation showed that this new abdominal concept 1) functions very much like any other collection system, 2) causes no greater incidence of urinary tract infection, 3) results in no identifiable adverse effects, and 4) is generally preferred over standard bed-side bags by the majority of patients. It is our conclusion that dependent drainage is requisite for neither 1) effective drainage or 2) the prevention of infections. The elastic properties of the bladder are such as to accommodate a bag worn on the abdomen and provide proper drainage.

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Traditionally investigators (1,2) have recommended the establishment of closed non-obstructed dependent drainage when a patient is catheterized and connected to a urinary drainage system. However, based upon known physiology coupled with the laws of fluid dynamics, this modality is not a requirement to successfully establish urine drainage. If a differential in pressure exists, urine flow will be established. Lapidès (3) points out in his "Fundamentals of Urology" that following the introduction of a very small amount of urine into the bladder, a rise in intravesical pressure results. The sharp rise in pressure reaches a plateau in the range of only 10-25cm of water even as the volume of urine within the bladder increases further. This plateau continues until the normal subject feels full (350-450 ml volume), at which time the pressure again begins to increase with additional volume. Zinner (4) reported that electromagnetic studies conducted on female patients showed intravesical pressures of 34-40 mm Hg during micturition, while von Garrelts (5) reported actual pressure values for males were approximately 45% greater. Additionally, Lapidès (6), Scott (7), and Anikios (8) confirmed the existence of intravesical pressures within this range. Such scientific experiments are supportive of ageless renderings that illustrate the projection of urine streams in a wide variety of arcs and distances by individuals of all ages and walks of life. It is clear then, that natural intravesicle pressure creates the differential necessary to promote urine flow, even of a level sufficient to permit urine to flow "uphill."

These facts should allow a new approach to urinary drainage. Specifically, abdominal level collection. Obviously, in the name of asepsis, retrograde flow is to be avoided. However, with a modern closed drainage system, complete with functional anti-reflux valve, this will not occur even when the reservoir is raised above the catheter outlet height. Furthermore, using modern drainage systems, several investigators

(9,10,11) have concluded that catheter-induced bladder infections do not occur intraluminally, but rather are primarily the result of bacteria migration extraluminally in the periurethral mucus sheath surrounding the catheter. We have evaluated a new urinary drainage system (*) designed to capitalize on intravesical pressure and worn on the abdomen.

Methods:

This study was designed to compare several aspects of a closed urine collection device worn on the abdomen with the standard bed-side or satchel system (2) used routinely at The University of Texas Medical Branch in Galveston Texas. Specifically, the Objectives of the study were:

1. Determine if the abdominal bag fills with urine when worn as specified by the manufacturer. That is, will urine flow "up-hill" ?
2. Determine the differences, if any, in infection rate; abdominal bag vs. standard bag
3. Determine the differences, if any, in residual urine volumes of the bladder; abdominal bag vs. standard bag.
4. Determine any other adverse effects as a result of using the abdominal bag .

(*) SECOND NATURE TM Abdominal Urine Bag, supplied by DevelopMed Corporation; Houston, Texas.

Shown in Figure 1 is the abdominal bag as used in our study. In general, the abdominal bag is similar in construction to the standard bed-side drainage system. That is, the bag is constructed of vinyl, approximately the same thickness as other systems. The bag contains an anti-reflux valve of the "flutter" type often seen on leg bags. The drain tube stub terminates in a twist valve which must 'be rotated in one direction to open, and the other direction to close after drainage. The upper part of the bag contains slots, through which a fabric-like belt is passed. The belt, when passed around the waist of a patient, supports the bag. The surface of the bag that comes in contact with the patient's abdomen is covered by a fabric-like material for reasons of comfort.

To be included in the study , the patient had to meet the following criteria:

1. sterile urine
2. anticipate indwelling foley catheterization for a least two days

The following patients were excluded:

1. children
2. pregnant women
3. patients who had recent bladder surgery
4. patients with external catheters

Patient Study:

Patients entering the study were randomly chosen and effectively alternated between abdominal bag and standard bag. They remained on the same bag throughout the duration of the study. once each patient was catheterized and connected to a bag, the system was not opened except for changing the catheter and/or bag, consistent with good medical practice. While ambulatory or sitting, patients with the abdominal bag wore the bag on the lower abdomen. A waist belt was used to secure the bag to the abdomen at a level very nearly equal to that of the bladder.

Patients using the standard satchel-style bag carried the device while walking and placed it on the floor or hung it from chair-side while sitting. While sleeping, patients using the abdominal bag were allowed to either wear the bag, place it on the bed (to the side or between the legs) , or hang it on the side of the bed. Patients utilizing the standard bed-side bag hung their bags at bed-side while lying down or sleeping. With the standard bags, collection of urine specimens was accomplished by needle aspiration through the integral sampling port, while with the abdominal bag, small gauge needles were used to puncture the catheter wall to directly access the lumen.

Ultrasound (US) examination of the bladder was initially used to determine residual volumes. Culture and sensitivity (C & S) tests were performed frequently, per a pre-arranged schedule, to identify particular strains of microorganisms as fully as possible. Patient questionnaires (PQ) and physician questionnaires (DQ) were completed. The data were taken at the time intervals as specified in Table 1.

Treatment of Bacteriuria:

If a patient developed a urinary tract infection, the time (in days) from baseline (day 0) was recorded, as was the colony count, organisms and sensitivity studies. Treatment was recorded in the patient's charts. Since bladder contractions and/or spasms sometimes accompany the use of a closed urinary drainage system, the physician and nursing staff were instructed to be alert for this possibility as well as observe patients for an other untoward development.

RESULTS:

Forty-one patients completed the study. Patients were limited to those who were cared for by physicians in the Division of Urology, or those admitted by other services where urological consultation was requested. The patient were randomized into the two treatment groups as shown in Table 2. As is the practice at our institution, it is desirable to remove the catheter from each patient as soon as possible.

Therefore, the number of days worn was not a variable that was controlled by the investigation, but rather individualized in each case. Table 2 also presents the aggregated values the days worn by the patient population. The profile relative to age and sex is shown in table 3.

As was to be expected, many of the patients were on medication prior being admitted. This treatment is summarized in table 4.

One of the areas of critical concern was that of residual urine. Prior to the evaluation, we speculated that residual urine might be present in the bladder, in order to maintain the driving force necessary to push urine "uphill" into a bag worn on the abdomen. For the first several patients, we used ultrasound imaging in an attempt to visualize any residual urine in the bladder. It became obvious that any residual volume was so small as to go undetected by ultrasound examination. We categorized these patients as having zero residual volume. Subsequently, we adopted a procedure

whereby actual measurement was performed.

Specifically, the abdominally-worn bag was drained, removed from the patient's waist, lowered below the bladder level and any residual urine entering the bag measured. In all cases, "residual" urine collected by this means was less than 10 cc.

Calculations indicate that fully 2 cc of urine could have been held within the lumen of the catheter. This fact, coupled with the natural urine production occurring during the process of bag manipulation, suggests that at least some urine should have drained into the bag anyway. This was exactly the case as evidenced by the results shown in Table 5. Clearly there appeared to be no difference in residual volumes, abdominal bags vs. control bags. It seems apparent that the elastic properties of the bladder play a major role in the establishment of stable conditions both within the bladder and when connected to an outside reservoir via a catheter. In this case, the mechanism proved quite adequate to fill a bag worn on the abdomen without any noticeable the retention of residual urine.

One of the key aspects to be observed was the incidence of urinary tract infection. Table 6 shows that the abdominal bag was no worse than the standard control bag. In fact, since the infections noted during days 1-3 for the abdominal bag were *Staphylococcus epidermidis*, probably caused by handling of the urine specimens. The only positive urinary tract infections were experienced at day 8 and day 14 for two of the patients. Furthermore, these occurred only after the drainage systems were opened in order to accomplish a bag change.

We were particularly watchful for any signs of contractions or spasms of the bladder.

None were observed during the evaluation. In use, the abdominal bags filled continuously, much like the standard closed urinary drainage systems used routinely in our institution. No retrograde flow was observed, attesting to the proper operation of the anti-reflux valves.

Subjectively speaking, our staff was pleased with the abdominal bags as were nearly all the patients. Active patients were quite pleased, in that feelings of self consciousness were eliminated since the bag could be concealed under a robe or gown. Also, they commented on the soft fabric backing as an important comfort feature.

Fundamentals of urologic practice suggest satisfactory performance of a urine collection device worn on the abdomen of a catheterized patient. Capitalizing upon the positive pressure maintained within the bladder, this type of device should be expected to fill. Urine drains well even if it passes through a catheter emanating from a male patient, whose catheter has been taped to the anterior wall of the abdomen. Such is common practice to relieve undue pressure on the penoscrotal angle of the urethra. Clearly, there is some limit to the height such as a reservoir can be raised and still properly function. But elevating the drainage bag to level of the abdomen is well within the range of normal physiologic intravesical pressure necessary to accomplish filling.

An evaluation was conducted on forty-one catheterized patients comparing the collection of urine 1) in a system that featured an abdominal level reservoir with 2) a standard bed-side drainage system. Since literature references specifying that any urine reservoir be maintained below the drainage site are rather abundant, one of the primary objectives was to determine whether an abdominal level reservoir did, in fact, work. We experienced no problem in the reservoir filling in all twenty-one patients using the

abdominal level bag. In use, the bags filled continuously, much like any other closed urinary drainage system. None of the abdominal level bags used exhibited any retrograde flow and residual urine within the bladder was essentially non-existent; so small in fact, that it could not be detected by ultrasound techniques. Certainly of primary importance was our finding that the incidence of urinary tract infections was essentially equal to that registered with the standard drainage system. Since our initial experiments provided these positive results, we are now extending our studies to include patients who have undergone bladder surgery and see no reason why pregnant women and children should not use such a bag .

Why then the recommendation that a drainage reservoir be in a dependent position, that is, below the level of the bladder? It would seem that the rationale behind this stipulation has been carried over from earlier systems, which were open and/or did not contain functional anti-reflux valves. Since our experiments showed that a urine drainage reservoir positioned on the abdomen functioned very much like any other quality close drainage system, and no greater incidence of infections were observed, it would seem that dogmatic support of dependent drainage for either of these reasons, is not warranted.

Certainly, in quest of preventing urinary tract infections, the most important criteria are:

- 1) the practice of sound catheter-care procedures (13,14,15)
- 2) a quality catheter (16) , and
- 3) a closed urinary drainage system with an effective (17,18,19,20) anti-reflux valve

Lastly, it was enlightening to experience the response of patients and staff to the abdominal level bag. Nearly all patients liked it, citing reasons of comfort, freedom of

their hands and reducing their feelings of self-consciousness. It would appear that abdominal level collection of urine is a viable alternative to other modalities currently in use and a technique often preferred by patients.

Tables:

<u>Table 1.</u>	<u>Data Schedule:</u>			<u>Questionnaire:</u>		
	<u>Day</u>	<u>C&S (bag)</u>	<u>C&S(bladder)</u>	<u>Ultrasound</u>	<u>Patient</u>	<u>Doctor</u>
	0		x			
	1	x	x	x		
	2	x	x			
	5	x	x			
	8	x	x	x		
	11	x	x			
	14 &/or last	x	x		x	x

<u>Table 2.</u>	<u>Evaluation Profile-Days Worn:</u>			
	<u>CUMULATIVE DAYS WORN:</u>			
	<u>Totals</u>	<u>1-3</u>	<u>4-7</u>	<u>>7</u>
Control Bag	20	16	3	1
<u>Abdominal Bag</u>	<u>21</u>	11	6	4
<u>Total</u>	<u>41</u>	<u>27</u>	<u>9</u>	<u>5</u>

<u>Table 3.</u>	<u>Evaluation Profile - Age & Sex:</u>					
	<u>18-30</u>	<u>31-40</u>	<u>41-50</u>	<u>51-60</u>	<u>61-70</u>	<u>>70</u>
<u>MALES:</u>						
Control Bag	1	1	3	3	1	7
<u>Abdominal Bag</u>	<u>2</u>		<u>3</u>	<u>3</u>	<u>3</u>	<u>4</u>
<u>Total Males</u>	<u>3</u>	<u>1</u>	<u>6</u>	<u>6</u>	<u>4</u>	<u>11</u>
<u>Females:</u>						
Control Bag				2	1	1
<u>Abdominal Bag</u>	<u>1</u>		<u>1</u>	<u>3</u>	<u>2</u>	<u>3</u>
<u>Total females</u>	<u>1</u>		<u>1</u>	<u>3</u>	<u>2</u>	<u>3</u>
<u>MALES & FEMALES:</u>						
<u>Total (41)</u>	<u>4</u>	<u>1</u>	<u>7</u>	<u>9</u>	<u>6</u>	<u>14</u>

<u>Table 3.</u>	<u>Evaluation Profile - Residual Urine</u>			
	<u>0-10</u>	<u>11-50</u>	<u>>50</u>	<u>Not Recorded</u>
Control Bag (20)	17			3
<u>Abd. Bag (21)</u>	<u>19</u>			<u>2</u>
<u>Totals (41)</u>	<u>36</u>			<u>5</u>

<u>Table 3.</u>	<u>Evaluation Profile - Days to First Positive Culture</u>				
	<u>Colonies/ml.</u>	<u>Baseline</u>	<u>1-3 Days</u>	<u>4-7 Days</u>	<u>>7 days</u>
<u>Control Bag:</u>	<u>< 10,000</u>				
(total 21)	10-100,000		1 (*3)	1 (*7)	
	>100,000	1 (*1)			
<u>Abdominal Bag</u>	<u>< 10,000</u>		1 (*4)		
(total 22)	10-100,000		2 (*5,6)		
	>100,000	1 (*2)			2 (*8,9)

NOTES: (*)

- *1 pt. #33 found to have non-sterile urine at baseline; eliminated from study
- *2 pt. #35 " " " " " "
- *3 pt. #5 " " " " on first day
- *4 pt. #3 day 2 found to have staph; probable skin contaminant
- *5 pt. #15 day 1 found to have staph; probable skin contaminant
- *6 pt. #41 day 2 found to have staph; probable skin contaminant
- *7 pt. #4 day 7
- *8 pt. #1 day 14; bag changed
- *9 pt. #6 day 8; bag changed

Two patients were eliminated because of positive cultures at beginning of study (*1, *2)
 Positive urine cultures were found in only four of 41 patients in the study (*3,*7,*8,*9)
 - two were in control bags (*3, *7) at days 1-3
- two were in abdominal bags (*4,*7), and these occurred only after the drainage systems were opened to change bags.

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