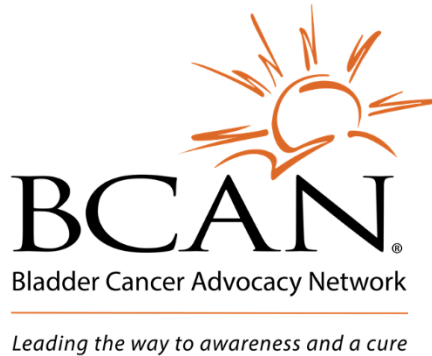


TREATMENT TALKS

What you need to know about long term management of urinary diversions



Managing Surgical and Mechanical Complications Long Term Diversion

Stephanie Chisolm:

Welcome to Treatment Talk, a live bladder cancer video chat from the Bladder Cancer Advocacy Network. These Treatment Talk discussions really are unique in that they feature medical experts. Tonight we have Dr. Kamal Pohar and Dr. Anne Schuckman with us. Also, some patient advocates to talk about their experience. They're really meant to increase your understanding of existing and new treatments across the spectrum of a bladder cancer diagnosis and to showcase patient questions that you can ask in advance to help you be empowered in making decisions regarding your treatment and care. Then we also want to highlight some current treatment advances for bladder cancer.

Today's Treatment Talk is really focused on the long term management of urinary diversions. Bladder removal is really the gold standard of care for people, especially with non-muscle invasive disease, who have high risk disease and it's getting closer and closer and obviously, for those with muscle invasive disease. We really wanted to try to showcase some of the long term issues that you should be aware of as you move forward if you haven't already had your diversion.

Dr. Anne Schuckman:

All right, great. Thank you so much, Stephanie. I'd just like to say thank you to BCAN, Morgan and Stephanie for inviting us tonight and giving us the opportunity to do this session. Want to say an especial thanks up front so I certainly don't forget, to Eric and Linda for being willing to come on this webinar with us and share their experiences. getting there. Okay, as Stephanie mentioned, tonight we're going to talk about urinary diversions

Goals of Urinary Diversion

- Preserve Function: Sexual, urinary, bowel
- Increase patient acceptance of cystectomy
- Allow timely adjuvant therapies
- Low rate of complications
- Best possible quality of life for patients

and really focus on long term complications associated with urinary diversions.

Dr. Anne Schuckman:

We're going to split this a little bit into two sections tonight. We're going to talk about mechanical or surgical type complications and then longer term, metabolic and infectious type complications. We'll jump right in.

As we all know, the goals of urinary diversion after bladder removal are to preserve function for patients. Whether that's sexual function, bowel function, or urinary function, to increase everybody's acceptance of getting a cystectomy if needed, allow timely use of adjuvant therapies after surgery, achieve low complication rates, and achieve the best quality of life for patients with a urinary diversion.

Options for reconstruction include an ileal conduit, an orthotopic neobladder, a continent cutaneous diversion, usually known as an Indiana pouch. These can be created either with an open technique or a robotic technique.

Short term complications can include things like urine leak, bowel leak, acute infection, or dehydration. We're not going to focus too much on that tonight. As I mentioned, we'll focus on mechanical issues such as uretero-ileal strictures, parastomal hernias or stomal stenosis. Functional issues such as incontinence, hypercontinence or retention and bowel dysfunction. Then non-mechanical issues such as metabolic problems, urinary stones or infections.

Uretero-ileal stricture is a type of problem that can happen regardless of the diversion type that you have. The incidence of this issue is about 5% to 15% in most described surgical series and usually this problem happens in the first year after your reconstructive surgery. What this problem is,

Options

- Ileal Conduit
- Orthotopic Ileal Neobladder
- Continent Cutaneous Diversion
- Can be created open or "robotic"

Short Term Complications

- Urine leak
- Bowel Leak
- Infection
- Dehydration

Long Term Complications

- Mechanical
 - Uretero-ileal stricture
 - Parastomal hernia
 - Stomal Stenosis (continent cutaneous)
- Functional
 - Incontinence
 - "Hypercontinence" (retention)
 - Bowel dysfunction

Long Term Complications

- Non-mechanical
 - Metabolic
 - Acidosis/bone health
 - Renal Function decline
 - Urinary tract infections/colonization
 - Stones

is a stricture that develops where the ureter is sewn onto the bowel segment used for the urinary diversion.

Dr. Anne Schuckman:

The way this presents is with dilation of the kidney system on the affected side and this can be picked up just on x-rays, such as this x-ray where we see one side is much bigger and more full of dye than the other, indicating poor drainage. Or it can be picked up due to recurrent urinary tract infections or a worsening of kidney function in the immediate post surgical year.

These strictures can be handled in several different ways.

Sometimes we're able to manage them what I call percutaneously. Either going through the back and placing an acrostomy tube directly into the kidney and then trying to come down from the kidney to the diversion to use a wire and either a laser or a balloon to dilate the stricture. These percutaneous type of interventions have a little bit lower success rate if the stricture happens to be on the left side, if it happens to be a longer stricture, or if that kidney's already not working too well.

Strictures can also be fixed just with going right back in either robotically or with an open surgery and reattaching the ureter to the urinary diversion. This usually involves cutting out the scarred part and then simply reattaching it. This works really well. Obviously, you need to undergo a surgery to have this done and so sometimes we try to delay this. But when we do have to resort to this, it's about a 93% success rate. Might be a little bit more successful if patients have not had a prior attempt at laser or balloon dilation. But again, it's a big surgery that people have to go through.

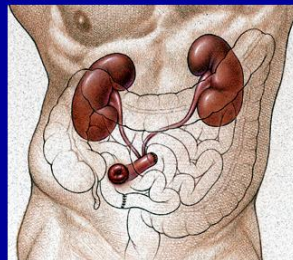
Let's focus now a little bit on some issues with ileal conduits or urostomies. I like this photo and it's really topical this week, since it's Halloween. A urinary conduit is urine that drains to a bag on your abdomen. This is a really happy patient. He has his stoma on the right side, looks like it's in good shape, his bag is hanging on in good position there and so is his jack-o'-lanterns.

Unfortunately, things aren't always quite this perfect. Patients can develop problems with a hernia

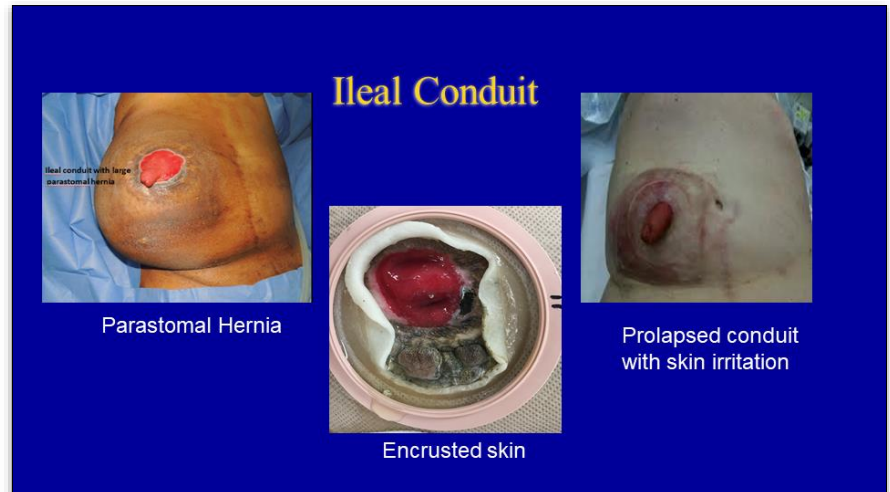
UI Stricture Repair

- Repair (mostly open in literature):
 - 93% success
 - May be more successful with NO PCNU (only PCNT)
 - May be morbid due to big surgery

Ileal Conduit (Urostomy) Issues



around the stoma, which can create issues with the bag staying in place. Potentially, it can create bowel problems with obstruction or diarrhea. Due to the contact of urine with the skin at the site of the stoma, patients can develop skin issues. This is really an extreme case where you see this encrusted skin and unfortunately, this patient had had some problems and then instead of coming to us, actually to deal with them, just kept cutting the hole bigger for the wafer and then more and more skin got affected.



Dr. Anne Schuckman:

Or patients can have problems with prolapse of the stoma and skin irritation. The prolapse is pretty uncommon. The skin irritation, I think is a fairly common issue.

Focusing on parastomal hernia, the incidence is really all over the map in studies that are done, anywhere from 4% to 50% in series. That's because probably only about, I don't know, 4% to 10% of patients may have any symptoms related to the hernia. But if you do CT scans, which everyone is having for surveillance for their cancer, there may be what's called a subclinical hernia, meaning it's there on the x-ray but you can't notice it as a patient and there's not any issues. Several things that can happen; maybe bowel obstruction, pain, bulge at the site or problems with the stoma bag leaking.

There are options for repairing a parastomal hernia. You can do this with the traditional open surgery where you either move the stoma to the opposite side and fix the hernia. There's minimally invasive ways to fix these hernias, going in if possible with either laparoscopic or robotic surgery and placing mesh inside the abdomen to block that hernia site,

Parastomal Hernia

- Incidence: 4-50%
- May cause several issues:
 - Bowel obstruction
 - Pain
 - “bulge”
 - Problems with stoma bag fit/leaking

Repair of PSH

- Open options
- Newer Minimally Invasive Options
- Move stoma to opposite side

but not moving the ileal conduit to the opposite side or to a new site.

Then because this can be such a big problem for patients, there have been several groups that have looked at ways to prevent this prophylactically. There have been several studies looking at putting in mesh actually at the time of surgery, at the time the creation of the conduit rather than waiting to have to fix the problem down the road. There was a study out of Sweden that showed actually with this prophylactic mesh placement, they were able to reduce the hernia rates by about half at the time of follow up for ileal conduit operation. We can talk more about this in the chat later.

Dr. Anne Schuckman:

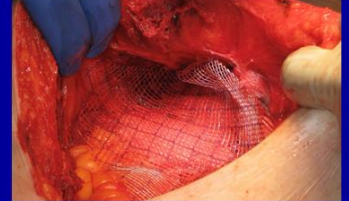
Again, possible disadvantages for urinary diversions and this is a patient choice tool that actually Dr. Pohar introduced me to several years ago. You can see that about 15% of patients complain of a symptomatic hernia and a very low number, 3%, may have some tightness of the stoma with an ileal conduit.

With what's called a continent cutaneous diversion, or a catheterizable stoma, there can be other types of complications. Usually these diversions are made out of colon and the stoma can be brought up either to the belly button as in this picture, or to a small stoma in the right lower quadrant. Then a patient passes a catheter through that stoma several times a day to empty the diversion.

Issues that can come up long term include leaking from the stoma or incontinence, stricture of the stoma or stenosis, or metabolic abnormalities just due to the nature of using colon as part of the diversion. Many of the issues with the stomas can be handled just in clinic or with a minimally invasive type of procedure under sedation. If there's a lot of leaking for the stoma, often we can inject things like collagen or other bulking agents in the submucosal area through a scope, either in the clinic or again,

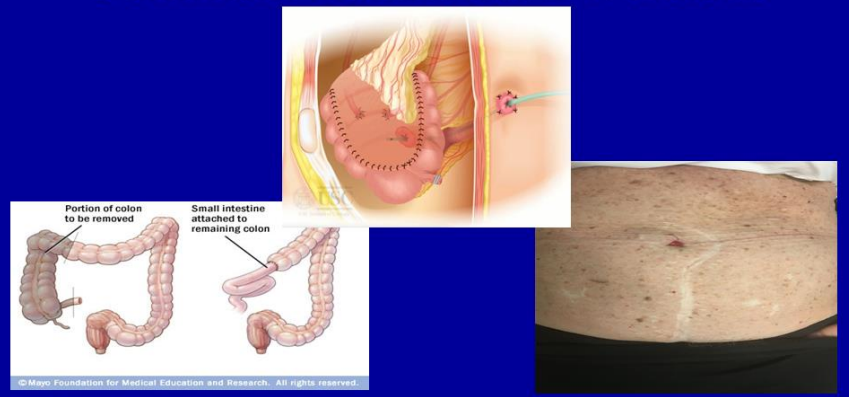
Hernia/Stenosis Prevention

- Prophylactic Mesh:
 - Swedish study showed a hazard ratio of 0.45 (confidence interval 0.24–0.86, $p = 0.02$)



Leidberg, Kollberg et al, EU, 78:5, 11/1/2020

Continent Cutaneous Diversion:



Indiana/R Colon Complications

- Stomal Incontinence
- Stomal Stenosis
- Metabolic Abnormalities (Hypokalemia more common)

under sedation in the operating room. If the stoma's too tight to put the catheter in, we can usually dilate this in the clinic or again, do a very small type of procedure under sedation, rather than having to revise the whole pouch. Major revisions are fairly rare with the Indiana pouches.

Dr. Anne Schuckman:

How about neobladders? The number one reason people often don't get a neobladder is for fear of complications. Whether this be a fear of incontinence or a fear of having to catheterize, patients are certainly on both ends of that spectrum.

We've looked at functional outcomes in lots of different hospitals and academic groups in terms of continence with neobladders. In the most ideal situation, institutions report about a 96% incidence of daytime continence and about a 75% incidence of nighttime continence. But this is really numbers that are created in high volume centers, high volume surgeons, potentially with the most perfect data collection.

We did a study at USC looking at continence in all comers for all male patients who have had orthotopic diversions, who are coming to see us for their follow up. So this wasn't really a selected group, it was just anyone coming into the clinic

with their follow up, regardless of how far they were out from the time of surgery. These are patients who had a cystectomy between 2000 and 2015 and we looked at about 200 patients. We gave patients a pad questionnaire to quantify what type of pad, how many pads, the size of the pad and we looked at different time intervals when we did the analysis.

Orthotopic Diversion

- Fear of Complications: #1 reason cited to patients not to perform continent diversion
 - Incontinence
 - Urinary Retention

Functional Outcomes-Continence

Original publications from pioneering institutions with excellent reported results

95.9% daytime continence

74.9% nighttime continence (J Urol, 1999)

--Most reports in the literature suggest continence rates are not this good -
--Nighttime continence generally reported to be much less

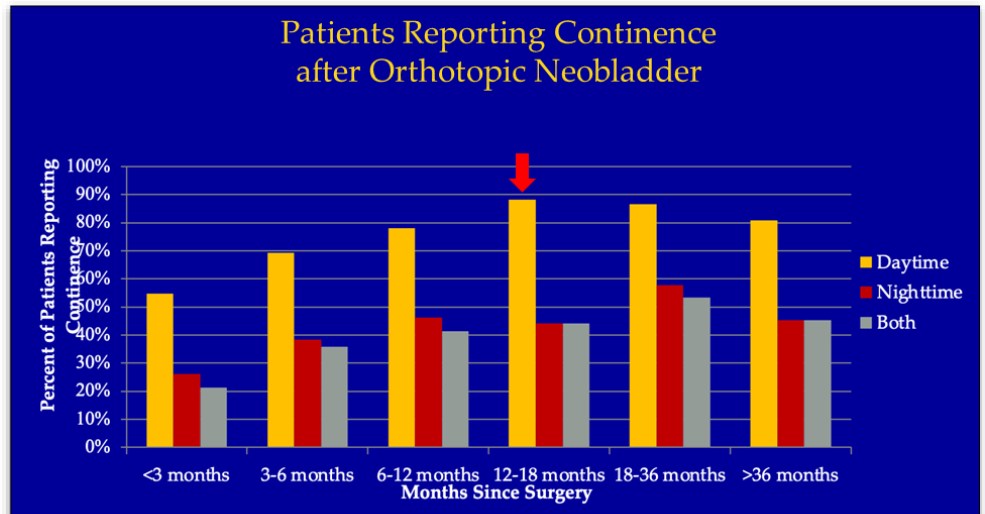
(methodology not consistent and objective measurement mostly lacking)

Interesting, what we found out is that really the daytime continence for males with neobladders didn't get to its peak point, which was about 88%, until 12 to 18 months after surgery. I think it's really important for providers and patients to know that the expectation is that this is a long game with the neobladder. It's not going to be perfect right away. I don't know if I can go back. With the nighttime continence in red there, you can see that actually it didn't peak until even longer, one and a half to three years after surgery. That number was around 60%. So there is more nighttime leaking than daytime leaking for patients.

The catheterization rate for our neobladder patients long term was quite low in men, only about 13%. But most men didn't have to start catheterizing right away. Many didn't have to start catheterizing again, until almost a year and a half after surgery.

Dr. Anne Schuckman:

In women, the catheterization rates with neobladders are much higher. This study states numbers almost as high 70% or 80%, but I think that most series state that the numbers are more around 20% to 30% of women who may need to catheterize.



Results

- Overall **catheterization** rate in the cohort was **13%**
- Median time to catheterization was 15.9 months
- No QOL component to this study

Functional outcomes in women

Table 4 Functional outcomes in women undergoing RC and orthotopic reconstruction.

Reference	Number of women	Median follow-up, months	Continence rate, % or n/N	Catheterisation, % or n/N	Continent during day and night, % or n/N
Ali-el-Dein, B; 2002 [4]	60	20	93	84	14
Arai, Y; 1999 [28]	12	33	10/12	4/12	4/12
Hautmann, R; 2000 [29]	42	NR	86*	NR	47
Stenzl, A; 2001 [30]	102	24	82	72	12
Stein, J; 2002 [31]	88	30	75-78***	NR	44-58**

NR, not reported; *Percentage of patients reporting continence both during the day and at night; **Range based on chart review and patient questionnaire.

RK Lee, HA Enein, W Artibani, B Bochner, G Dalbagni, S Daneshmand, Y Fradet, RE Hautmann, CT Lee, SP Lerner, A Pycha, KD Sievert, A Stenzl, G Thalmann, SF Shariat. *Urinary diversion after radical cystectomy for bladder cancer: options, patient selection, and outcomes.* BJU Int 2014; 113: 11-23.

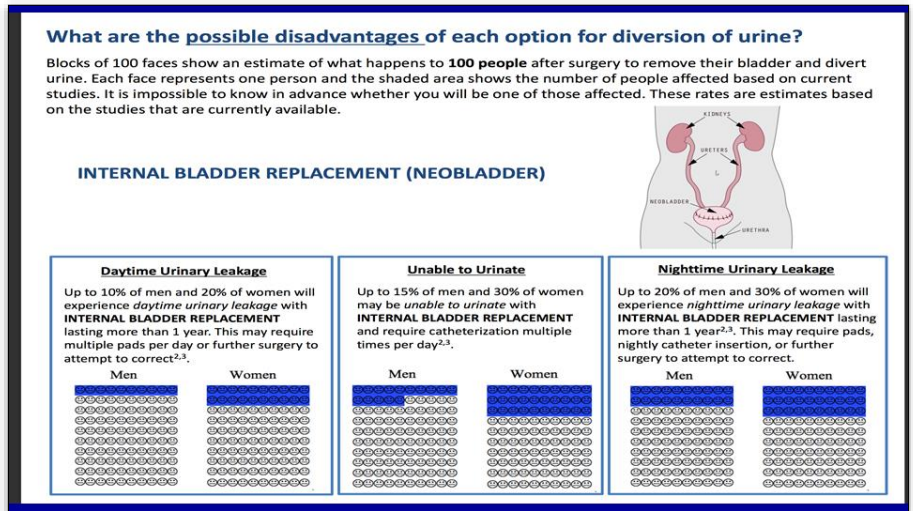
We've looked at what we can do in terms of surgical innovation to try to prevent hypercontinence or retention in women patients undergoing neobladder surgery. We're starting to really look more extensively at whether preserving the female sexual organs, such as the uterus and the vagina, may help create a more natural pelvic support system that would help women void better with a neobladder. Or whether doing some sort of reconstruction with essentially using some techniques from gynecology, such as a sacrocolpopexy might help to create a better situation for women to avoid having to use intermittent catheterization.

Again, from the patient choice tool, you can see that really problematic issues with daytime urinary leakage for men are about 10%, for women about 20%. Catheterization rates really line up quite well with what we saw at USC. For men, about 15% and women, about 30%, but more people do have leakage at night, as seen in that last frame. I actually think that sounds a little low compared to my clinical experience.

Hypercontinence-Can we Prevent it?

Uterus/vaginal-sparing radical cystectomy when feasible?

Sacrocolpopexy?



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