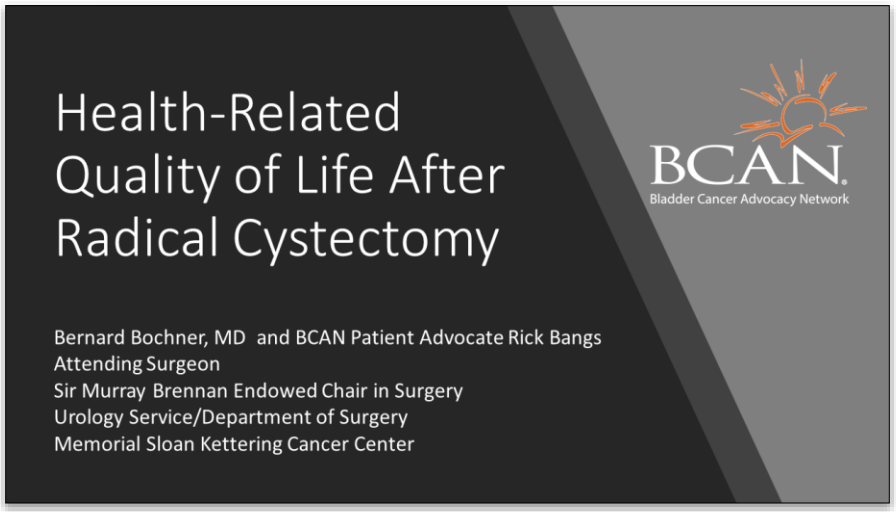


Stephanie Chisolm:

Welcome to health-related quality of life after radical cystectomy. Today, we're going to look into what a large study tells us about the new normal after bladder cancer. So bladder removal surgery, or a radical cystectomy is the gold standard of treatment for many people with high-risk bladder cancer and BCAN often gets questions about, what would my life be like after cystectomy?

Today, we're really delighted to have Dr. Bernie Bochner and other experts. He's representing the Memorial Sloan Kettering to talk about the long-term impact of bladder removal surgery on a patient's quality of life. We're also really happy to have voice of Bladder Cancer Matters, patient advocate, Rick Bangs here to find out what the surveys and interviews of more than 400 people tell us about longer term quality of life with an ileal conduit or a continent urinary diversion. So welcome, Dr. Bochner. And welcome, Rick. It's nice to have you both here.

Stephanie Chisolm:

Well, Rick you talk about in Bladder Cancer Matters that you're a proud owner of a 2006 model neo-bladder. Let's start with you. That's quite a surgery. What were some of the concerns that you had about how your life would change before you had a radical cystectomy?

Rick Bangs:

So I think for me, radical cystectomy was my second surgery in my entire life, so obviously I had concerns about surgery, but I think there are three things that I was concerned about in terms of my quality of life. The first, is that I had very significant concerns about self-catheterization. I would say, almost, I was freaking out. It was just something I just couldn't imagine myself doing. The second thing is obviously I was concerned about continence because I was going to have a neo-bladder and would it retain urine? And how is this thing going to work? And how well was it going to work? And I think the third thing for me was sexual function and how that was going to work or even if it was going to work. So those would be my three major areas of concern as a patient.

Stephanie Chisolm:

Right. And those were things that were covered in this study. So Dr. Bochner, congratulations on getting this published. It's a really important study to look at the long-term quality of life of patients who go through radical cystectomy. As a urologist at Memorial Sloan Kettering Cancer Center, you've done a lot of radical cystectomies in your career. Why did you think it was important to do this study? And what did you hope to learn by surveying all these participants?

Dr. Bochner:

Stephanie, great question. First of all, I want to thank you and Rick and the whole BCAN group for putting this really important discussion together. A lot of us in the medical field, treating bladder cancer spend a lot of time focusing on the cancer management side of things. Obviously our number one goal here is to get this cancer out, treat the entire body and really try to provide people an opportunity to walk away from this. But as you do more and more of these surgeries, you recognize that it has the potential for a lot of changes in people's lives over time. And as we've gotten better with delivering more effective therapy, we see people living longer, more people living longer, and our second goal is to make sure that they can go on and live full and productive lives, to get back to the things that they want to do.

Dr. Bochner:

And as we look back at sort of the previous evaluations of how quality life is affected after surgery, you realize that there's not a lot of great data available. And in large part, it sort of stems from the fact that there are not a lot of great tools to be able to kind of help measure that quality of life, especially given the diversity of people that will have this disease and undergo care. So Rick is a perfect example, probably of the sort of prototypical person that would have bladder cancer, a male, much more common than female. And usually, folks in their mid-sixties or so is typical when bladder cancer gets diagnosed, but obviously, it can happen in women, it can happen in younger people, it can happen in much older people. And there are so many different things that are happening in people's lives.

So to ask the same questions, for instance, in a 40-year-old, married woman, with younger kids and a job and a husband and the concerns that she may have to undergo a major surgery compared to, let's say, somebody who's in their late seventies, who's a male, he's retired, maybe he's lost his spouse at that point, he's not working anymore. So the concerns are so different. And what we need as physicians is to be able to better understand the specific concerns that people have. And then we could begin to sort of address how surgery ends up affecting them. I think in the past, the perception was that this kind of surgery led to a big black hole. As Rick had mentioned, there are so many unknowns when you take somebody who otherwise is relatively healthy, maybe hasn't experienced a major health issue and hasn't undergone major surgery. It's like, what's on the other side of this? And one big aspect of doing the study was to provide not the doctor's interpretation of what is happening, but to use actual feedback from the patients, right? So that was kind of how we designed the study.

Stephanie Chisolm:

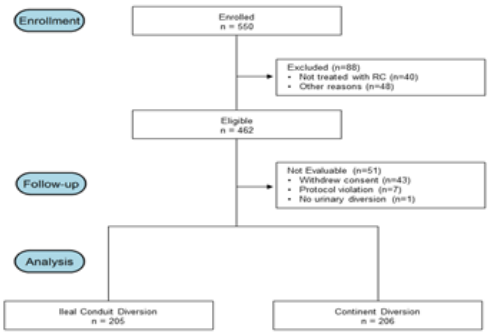
Great. Well, we're really excited to learn more about it. So why don't you go ahead and share your screen and give us some high points and any surprises that you found as you did the study.

Bladder Cancer

Health-related Quality of Life for Patients Undergoing Radical Cystectomy: Results of a Large Prospective Cohort

Matthew B. Clements [a], Thomas M. Atkinson [b], Guido M. Dalbagni [a], Yuelin Li [b], Andrew J. Vickers [c], Harry W. Herr [a], S. Machele Donat [a], Jaspreet S. Sandhu [a], Daniel S. Sjoberg [c], Amy L. Tin [c], Bruce D. Rapkin [d], Bernard H. Bochner [a,]*

- Single-center prospective study enrolling M_0 patients scheduled for RC or preop chemotherapy
- Choice of urinary diversion per standard of care
- Collected 14 validated patient-reported outcome measures at baseline, 3-, 6-, 12-, 18-, and 24-months post-RC



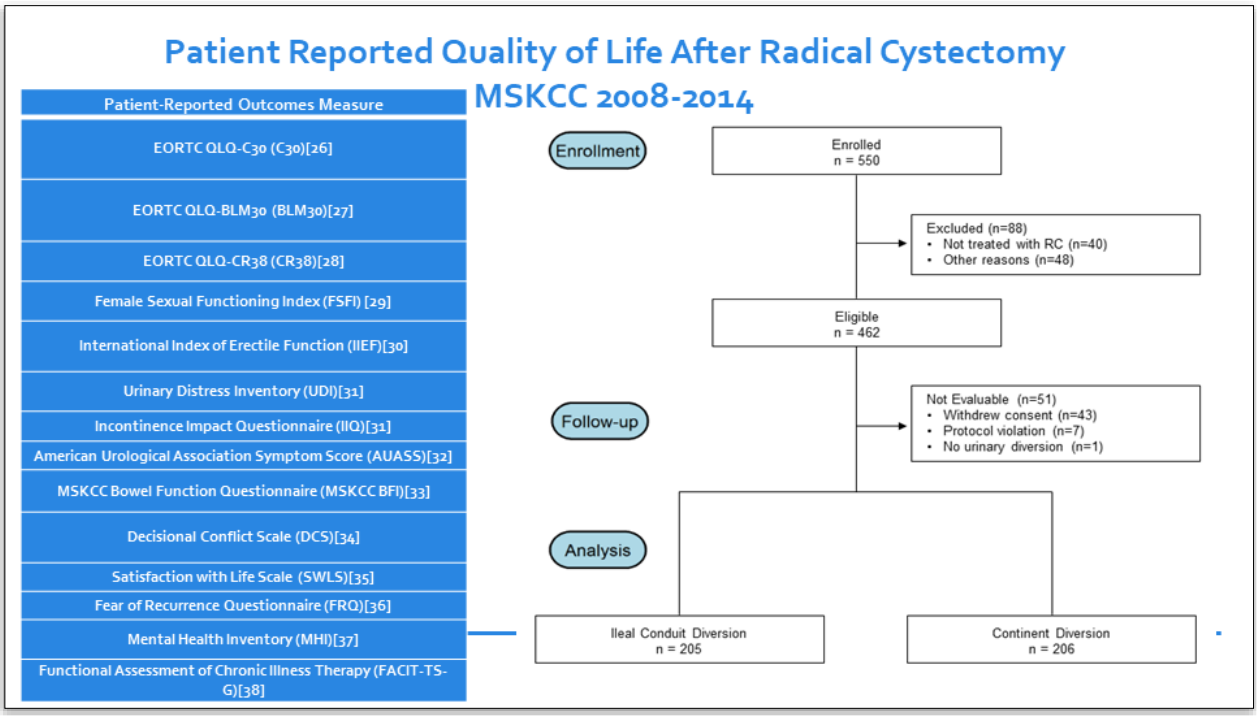
Memorial Sloan Kettering Cancer Center

Clements et al, Eur Urol. 2021

Dr. Bochner:

Okay. So this is a study that had recently been published and a current fellow of ours, Matt Clements had been terrific at helping to put a lot of this data, but this is really a study that we had started back in 2008. Took several years to accrue. This was all done at Memorial Sloan Kettering. So it's our institutional evaluation. And basically the people that we wanted to enroll were everybody who is eligible for a potentially curative, radical cystectomy, whether they received chemotherapy before surgery or not, they were eligible to enroll. We know that the choice of a reconstruction of the urinary system can be a very personalized decision. And it's kind of a shared decision between a patient and the physician. So it's not randomly assigned, but the choice of diversion was really per the standard of care between the patient and their doctor.

We used a whole battery of what's called validated patient-reported outcome measures. And so these are a series of questions that have really been studied and have been shown to be able to provide consistent information in the way people answer the questions. And we'll show you the various measures that we used. One of the unique natures of this particular study is that we got sort of how people were doing before their procedure. So it wasn't a snapshot after surgery, how you're doing, we really got a baseline measurement. So we got a sense as to what the changes were after surgery itself. The immediate period, right after surgery, as you could imagine, undergoing any kind of major surgery there's a recovery period from the surgery itself. And that's been pretty well documented following radical cystectomy. And most of the time complications and things like that pretty well collected up to about 90 days.



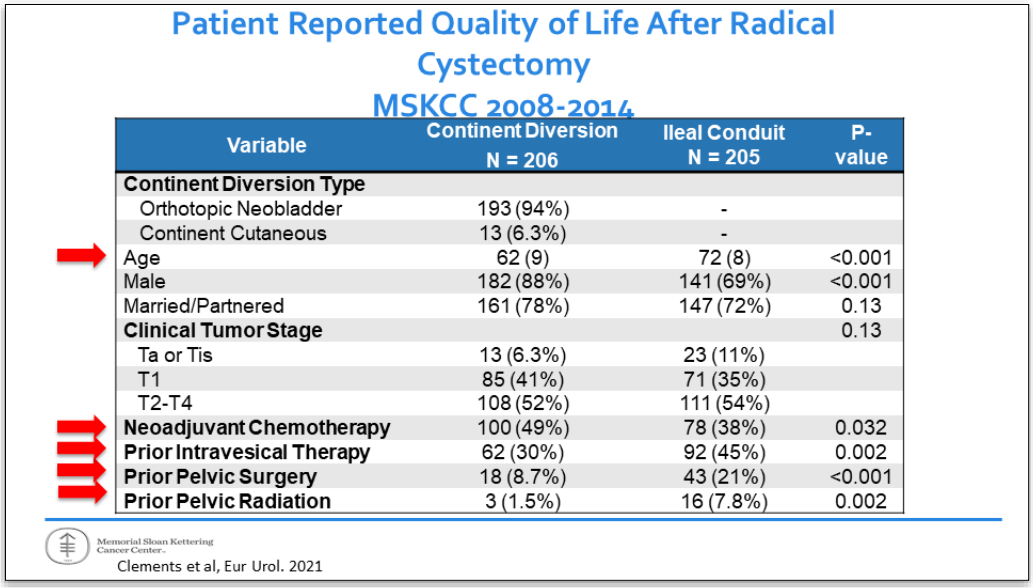
Dr. Bochner:

And so what we wanted to ask is, well, let's see what happens after that? After people get over that kind of expected recovery from the surgery itself, how do they go on to rejoin their lives? And so what we did was we use these measures at three months, six months, one year, a year and a half, and then two years after surgery. We figured that that really kind of gave us a pretty good sense as to how things were covered. And what we did was we enrolled 550 patients, so pretty large study. And at that point, we needed baseline measurements. Some of the patients did not fill out all the baseline measurements. And so the eligible group for the analysis was a little bit lower. Ultimately, what we were left with was about just over 200 patients that underwent ileal conduit, urinary diversions, that's the diversion that requires the external bag. And about 200 patients that had continent diversions, the vast majority of those were neo-bladder patients. This is the reconstructed bladder to the urethra itself.

I've listed here some of the measures that were used just to kind of show you the diversity of things that we were looking for. So there are standardized, validated measures if you will, that measure different parts of quality of life. And they can include things like sexual function, and there's separate measures for females and for males, measures of urinary distress or incontinence, bowel function, because the GI system can be affected by the surgery. And then we looked at other things like decisional conflict scales, or satisfaction with life, fear of recurrence and other mental health inventories. So it was a real sort of diverse look using a variety of measures to try and identify kind of how people are doing overall.

The study was to designed look at the two groups of diversion patients differently, okay? And it wasn't really to compare, how did the continent diversion or neo-bladder patients do to the conduit patients? It's because they're different groups of patients. There's a selection process as to who gets what. And so we know that in general neo-bladder patients are going to be younger. And in this study, they were actually 10 years younger than the patients undergoing ileal conduits.

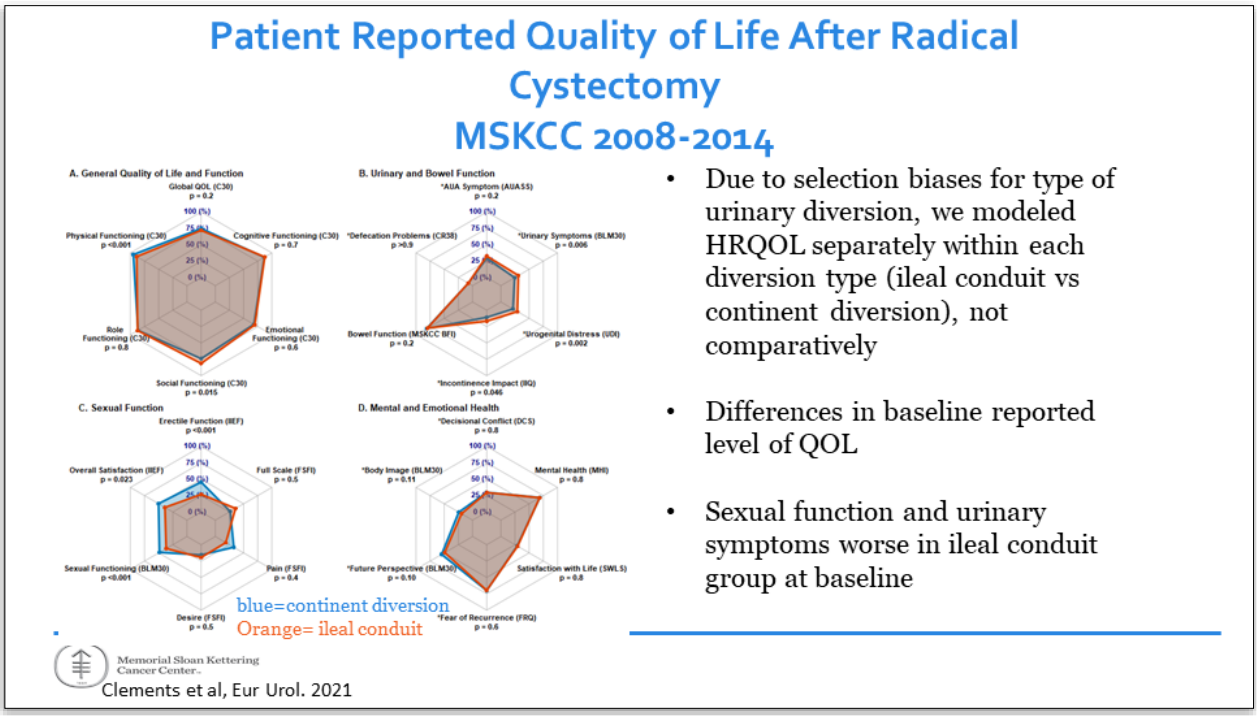
Dr. Bochner:



Variable	Continent Diversion N = 206	Ileal Conduit N = 205	P-value
Continent Diversion Type			
Orthotopic Neobladder	193 (94%)	-	
Continent Cutaneous	13 (6.3%)	-	
Age	62 (9)	72 (8)	<0.001
Male	182 (88%)	141 (69%)	<0.001
Married/Partnered	161 (78%)	147 (72%)	0.13
Clinical Tumor Stage			0.13
Ta or Tis	13 (6.3%)	23 (11%)	
T1	85 (41%)	71 (35%)	
T2-T4	108 (52%)	111 (54%)	
Neoadjuvant Chemotherapy	100 (49%)	78 (38%)	0.032
Prior Intravesical Therapy	62 (30%)	92 (45%)	0.002
Prior Pelvic Surgery	18 (8.7%)	43 (21%)	<0.001
Prior Pelvic Radiation	3 (1.5%)	16 (7.8%)	0.002

The continent diversion patients were more likely to have better renal function, fewer underlying illnesses. And because they had healthier kidneys, a greater percentage of patients getting neo-bladders actually received chemotherapy prior to surgery as well, okay? In contrast, as I mentioned, the patients getting ileal conduits were a little bit older, they were more likely to have undergone previous washings within the bladder, intravesical therapies, there was a greater percentage of folks that had had pelvic radiation therapy. And so maybe that was one of the selection criteria for the conduits, and they were more likely to have pelvic surgery in general as well.

So just if you kind of look at the groups, you can tell that they're quite different. So really what we wanted to do with this study was to show more of the trajectory after surgery, as opposed to separating the groups for direct comparison. So I don't want this to be looked at as, well, continent diversions are better or worse than conduits. That's really not what this particular study is designed to answer.



Dr. Bochner:

So these plots here, basically these are called spider plots, but basically what we're trying to do is put a huge amount of information on these graphs here to try and get a sense as to how the baseline measurements of quality of life also differed between the two groups, right? So we have kind of a younger, healthier group of neo-bladder patients, many more that got preoperative chemo versus an older group, maybe a few more medical complications in the ileal conduit group. And a couple things stood out in the baseline measurements that showed that there were also some major differences. Sexual function, for instance, was really significantly different between the two groups. As you would expect, the younger men had better sexual function, overall satisfaction with their sexual function compared to the older group of folks. The ileal conduit patients, prior to surgery, had greater degree of urinary voiding symptoms, again, not unexpected in an older group of men. So again, these were kind of important baseline differences to take a look at.

I think it's important to mention that the majority of folks in this particular study are men. And that's not unusual because men are much more likely to get bladder cancer and undergo treatment for it than women. It's more common in men. And so, not unexpected that we would have that higher male to female ratio.

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