# IMPROVING OUTCOMES IN RADICAL CYSTECTOMY

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# Cystectomy: M&M

• 90-day complication rate: 64%- 78%

- Clavien: 0 (36%), 1-2 (51%), 3-5 (13%)

- 29% GI, 25% infectious, 15% wound

• 90-day readmission rate: 25-43%

• 90-day mortality rate: 7%-10%

Challenge = Opportunity for Quality Improvement

Shabsigh et al., Eur Urol 2009; Stimson et al, J Urol 2011

# **Improving Outcomes**

- Refining Multimodal Therapy
  - Improving utilization of perioperative chemo
  - Development of new agents
- Improving Peri-operative Outcomes
  - Clinical care pathways
  - Refining the role of Robotics
  - Overcoming obstacles to optimal care

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# Improving Outcomes

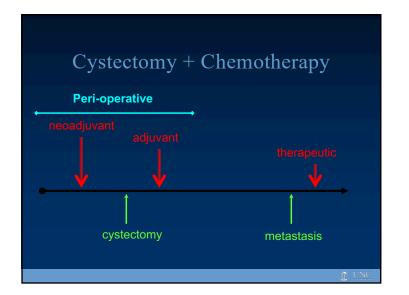
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# Radical Cystectomy

- Cystectomy provides best treatment for localized disease
- Is it possible to improve outcomes with peri-operative chemotherapy?

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# Cystectomy + Chemotherapy

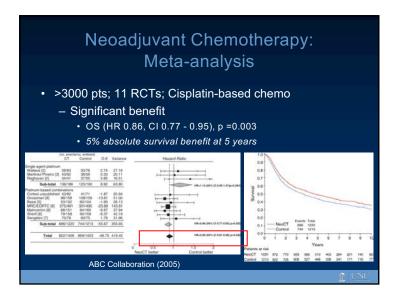
- Rationale for early chemotherapy
  - Early treatment of micrometastatic disease
  - Increased chemosensitivity of small volume tumors
  - Inverse relationship of tumor burden + cure
  - Ascertain chemosensitivity



# Cystectomy + Chemotherapy neoadjuvant adjuvant therapeutic cystectomy metastasis

# Neoadjuvant Chemotherapy: Potential Benefits

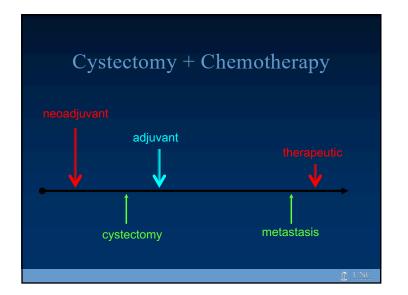
- Early treatment of occult metastases
- Downstaging primary tumor
  - Pathologic response rates = 60-70%
  - P0 in 25-38% patients
  - unresectable → resectable
- Possible to assess response
- · Survival benefit



# Neoadjuvant Chemotherapy

- Platinum-based therapies
  - MVAC, CMV, Gem-cisplat
  - Carbo is not an effective substitute
- 3 cycles X 28 days/cycle
- Approx. delay in surgery = 4 months.





# Adjuvant Chemotherapy: Potential Benefits

- · Early treatment of occult metastatic disease
- Need for treatment based on pathologic (not clinical) criteria
  - Staging error of cT vs. pT
  - Avoid toxicities in those potentially-cured by surgery
- · Minimal tumor volume
- · ? Survival benefit



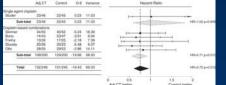
# Adjuvant Chemotherapy

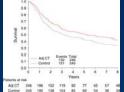
- Potential Deficits
  - Inability to assess response
  - Enhanced toxicity (after surgery)
  - Delay in receipt of systemic therapy



# Adjuvant Chemotherapy: Meta-analysis

- 491 pts; 6 RCTs; Cisplatin-based chemo
  - Significant benefit
    - OS (HR 0.75, CI 0.60 0.96), p =0.019
    - 9% absolute survival benefit at 5 years





ABC Collaboration (2006)



# Perioperative Chemotherapy

- Increased use of platinum-based peri-operative chemotherapy
  - 12% (1997-2003) → 30% (2003-2007) per NCDB
  - 2% → 23% in Alberta GU Onc Grp after establishing CPG
- BCAN QoC Survey: n=4541 (Feifer, AUA 2011 #405)
  - 34% (12% NAC, 22% AC); 35% non-Cis-Pt regimens
- Neoadjuvant versus adjuvant still uncertain
- Need for alternative (less toxic) agents



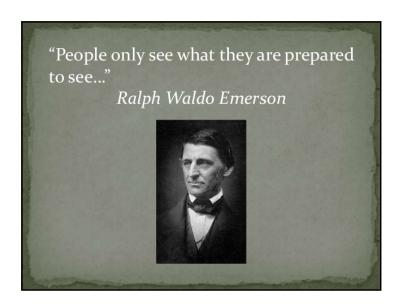
# Radical Cystectomy: 2018

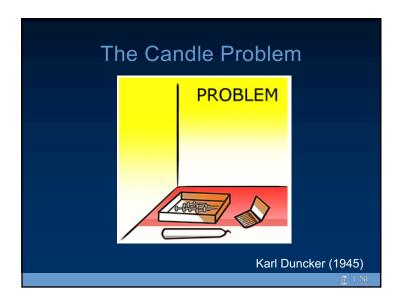
- Refining Multimodal Therapy
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  - Development of new agents
- Innovation to improve peri-operative Outcomes
  - Clinical care pathways
  - Refining the role of Robotics
  - Overcoming obstacles to optimal care

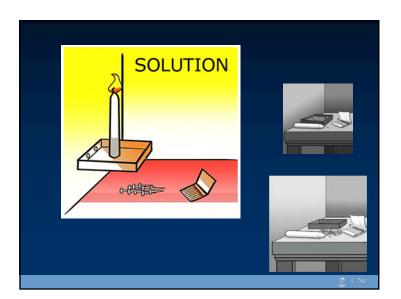


# Innovation

- Product innovation
  - e.g. robotics
- Process innovation
  - Care pathways
  - Telecare, outpatient management, task transfer







# Overcoming Functional Fixedness



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# Innovation

- Process innovation
  - Care pathways
  - Telecare, outpatient management, task transfer
- Product innovation
  - e.g. robotics

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# Care Pathways



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# Potential for Clinical Pathways

- Cost reduction
- Improve quality of care / error reduction
- Transparency of treatment
- Staff satisfaction
- Training/education
- Standardization



# **Cost Reduction**

- Most important for decision-makers / administrators
- · Focus of much research on CP
- · Cost reduction seen for all surgeries
  - Colorectal, hepatic, pancreatic, cardiac, ortho, transplant, bariatric, thoracic, hernia, obstetric, and urologic

Ruchlin (2001)
Chang (2005)
Ronellenfitsch (2006)
Melbert (2005)
Joh (2003)
Rouse (1998)

# **Cost Reduction**

- Length of Stay
- OR time
- · Parallelization of processes
- Diagnostic tests
- Materials
  - Surgical equipment, meds
- Avoid duplication

Ruchlin (2001) Chang (2005) Ronellenfitsch (2008)



# **Quality of Care**

- Morbidity
  - Decrease pneumonia, nausea, wound infections, overall complications (error reduction)
  - Early NGT removal and feeding
  - Mortality

Lemmens (2008)
Pruthi (2004)
Chang (2001)
Ronellenfitsch (2008)
Pitt (1999)



# Transparency of Treatment

- Structure and organization
- · Steps in a well-defined continuum
  - Available
  - Documented
  - Evidenced-based
- · Physicians, staff, patients

Parker (1999) Holzbeierlein (2000)

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# Staff Training / Satisfaction

- Education implementation of structured, evidencedbased approaches
  - Move away from "guild" system
  - Mode of translating scientific evidence to clinical practice in multidisciplinary setting
- · CP lead to increased staff satisfaction
- Increased quality of care --> increased staff satisfaction

Goede (1995) Holzbeierlein (2000) Ronellenfitsch (2008)



# Which cases make sense?

- · High volume
- · Relatively complex
- · Resource intensive
- · Potential for variation
- High morbidity
- ★ Radical Cystectomy

Ruchlin (2001) Ronellenfitsch (2008) Melbert (2005)



# University of North Carolina Clinical Care Pathway for Radical Cystectomy

- Pre-op counseling
  - Probably the most important step
  - Inform about clinical pathway and what to expect
  - Provide pre-op literature regarding peri-operative course
  - Expected hospital stay should be 4 days
    - If you tell them a week they will stay a week

Pruthi (2003)



# **General Concepts**

- Antibiotics
  - 24 hrs peri-operative
  - Start within 1 hr before incision
  - Ertapenem or Ancef/Flagyl
- Cardiovascular
  - Anti-coagulation / anti-platelet therapy
  - Development institutional policy w/ cards and anesthesia

# **General Concepts**

- DVT/PE prophylaxis
  - Early and frequent ambulation
  - TED / SCD
  - SQ Heparin or Lovenox
- Pulmonary
  - IS -- little data to support use, but inexpensive (< \$5)</li>
- Multi-modal use of non-narcotic analgesics



# Pre-op

- · Bowel prep
  - Regular diet all day before; NPO after MN
  - Fleets® enema morning of surgery
- No pre-op admission
- Antibiotics
  - 24 hrs peri-operative Start within 1 hr before incision
  - Ertapenem or Ancef/Flagyl
  - Pregabalin (Lyrica) 150 mg po
- Alvimopan po
- VTE prophylaxis begun pre-op in holding area
  - Heparin SQ 5000 units



# Day of Surgery

- OG removed at end of case
- Use of Exparel 20 mg SQ -- ? Better than bupivicaine ?
- Post-op labs DVT/PE Ambulation; TED/SCD
- Pulmonary IS
- Pain
  - IV Ketorolac 30mg IV then 15mg IV q 6h X 48h (if renal function OK)
  - (and/or IV Acetaminophen)
  - Pregabalin (Lyrica) 75mg bid
  - IV narcotics (MSO4) prn
- GI
  - PPI until D/C
  - Alvimopan
  - Pro-motility agents metoclopramide (less N/V)
- Diet -- NPO
- Catheter / drain management

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# **POD #1**

- AM labs
- Antibiotics -- peri-op X 24h
- DVT/PE Ambulation; TED/SCD; start lovenox or heparin SQ
- Pulmonary IS
- Pain
  - Ketorolac
  - Pregabalin (Lyrica) 75mg bid
  - (and/or IV Acetaminophen)
  - IV narcotics (MSO4) prn
- GI -- PPI; metoclopramide; alvimopan; chewing gum
- Diet clears (irrespective of bowel function)
- Catheter / stoma / drain management and teaching
- Discharge planning



# **POD #2**

- (AM labs prn)
- DVT/PE Ambulation; TED/SCD (LMWH)
- Pulmonary IS
- Pain
  - Convert to po meds (oxycodone/acetaminophen; celecoxib, lyrica
  - IV narcotics (MSO4) prn
- GI -- PPI; metoclopramide; stool softener; alvimopan; chewing gum
- Diet -- clears (irrespective of bowel function)
- Catheter / stoma / drain management and teaching
- Discharge planning



# **POD #3**

- AM labs
- DVT/PE Ambulation; TED/SCD (LMWH)
- Pulmonary IS
- Pain
  - po meds (oxycodone/acetaminophen; celecoxib, lyrica)
  - IV narcotics (MSO4) prn
- GI -- PPI; stool softener; chewing gum
- Diet regular diet (irrespective of bowel function)
- Catheter / stoma / drain management and teaching
- Discharge planning


# **POD #4**

- (AM labs prn)
- DVT/PE Ambulation; TED/SCD (LMWH)
- Pulmonary IS
- Pain
  - po meds (oxycodone/acetaminophen; celecoxib, lyrica)
- GI -- PPI; stool softener; chewing gum
- Diet -- regular diet
- Catheter / stoma / drain management and teaching
- Discharge planning
- ? Discharge



# Discharge

- Remove drain (unless leak)
- Meds
  - Pain meds (e.g. oxycodone/acetaminophen) = #15
  - (median use = 10 (+/- 4))
  - Pregabalin (Lyrica) 75mg bid X 2 weeks
  - Celecoxib 200mg bid X 2 weeks
  - Stool softener
  - Resume ASA
- VTE prophylaxis Lovenox 40 mq SQ X 4 weeks
- Catheter / stoma teaching
- Home health coordination
- RTC POD #7-10 for stent removal
- (RTC 2-3 wks for cystogram + catheter removal for neobladder)



# **UNC** Experience

	2004-2005	1999-2000	1996-1997
ICU stay (days)	0.0	0.8	1.8
Time (days) to clears	2.0	5.3	6.9
Time (days) to reg diet	3.9	7.9	8.3
Time (days) to D/C	5.1	10.0	11.2
Day of Discharge (%)			
-POD 4-5	79%	0%	0%
-POD 6-7	17%	23%	13%
-POD > 8	4%	77%	87%
Hospital costs	\$4290	\$10375	\$13155
OR costs	\$3480	\$5069	\$6257
Total costs	\$7770	\$15444	\$19412

Evans (2005)



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# Summary Points: Clinical Pathways

- Positive effects on:
  - Quality of care
  - Health care costs
  - Education
  - Staff satisfaction
  - Patient expectations
  - Translating scientific evidence to clinical practice
- · Encourage more widespread use in urologic surgery
  - Multidisciplinary fashion led by surgeon

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# Improving Outcomes in Radical Cystectomy

- · Clinical care pathways
  - Method to improve outcomes and reduce costs
- Role of robotics/minimally-invasive surgery

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# Robotic Cystectomy

- Has emerged from growing experience with robotic assisted prostatectomy
- May offer viable alternative to open radical cystectomy in select patients

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# Benefits of Minimally-invasive Surgery

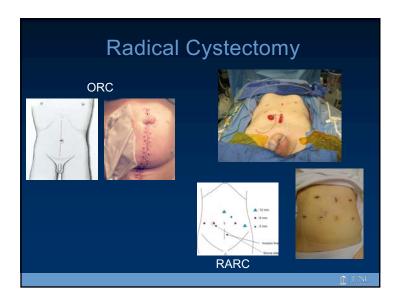


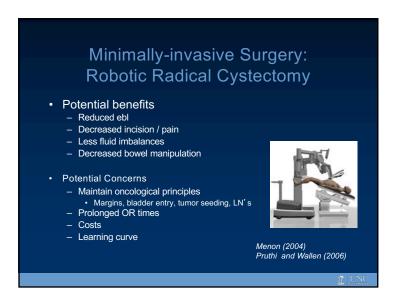
choleycystectomy

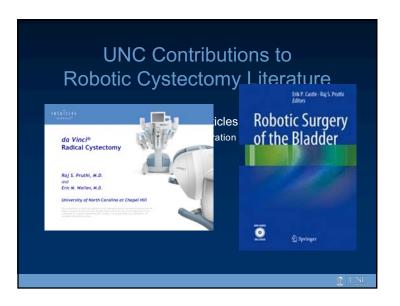


nephrectomy

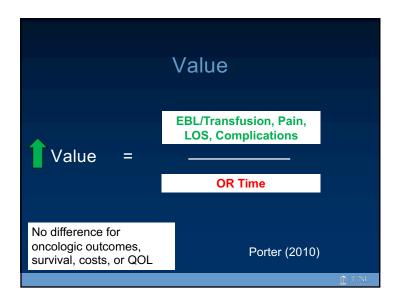
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# Summary: Robotic Cystectomy

- Improves patient outcomes EBL, transfusions, pain, LOS, and complications
- Provides thorough extirpative procedure preserves oncologic integrity
- · Increases in OR time

Adds value to care of patients undergoing radical cystectomy

# Future Directions Increased worldwide experience Long-term oncologic assessment Multi-institutional RCT Intracorporeal urinary diversion

# Robotic-assisted Laparoscopic Intracorporeal Urinary Diversion

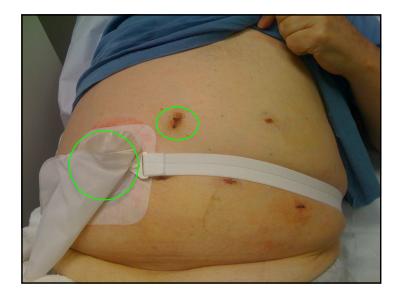


Pruthi (Eur Urol) (2010)

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UNC	nitial Ex	perienc	e
	IC Diversion (n=40)	EC Diversion (n=40)	p value
Mean EBL (range)	223 (50-400)	266 (50-900)	0.304
Mean OR Time (range)	5.3 hrs (3.9 – 7.3 hrs)	4.2 hrs (3.8 – 4.8 hrs)	< 0.001
Post-op			
Mean time to flatus	2.2 d	2.4 d	0.427
Mean time to BM	3.1 d	3.3 d	0.762
Mean time to DC	4.5 d	5.2 d	0.209
Inpatient narc use (MSO4 eq)	57.6	93.2	0.034

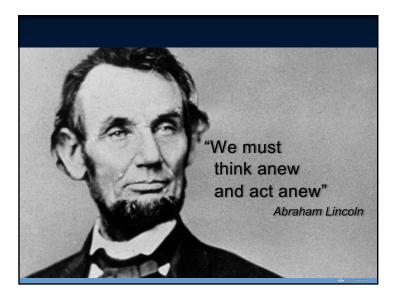




# Improving Outcomes in Radical Cystectomy

- Clinical care pathways
  - Method to improve outcomes and reduce costs
- Role of robotics/minimally-invasive surgery
- Overcoming obstacles to optimal care

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# Obstacles to optimal healthcare delivery in bladder cancer

- Travel Distance
- Financial Toxicity
- Nutrition

# Obstacles to optimal healthcare delivery in bladder cancer

- Travel Distance
- Financial Toxicity
- Nutrition



### **Travel Distance**

- National trend toward regionalization of health care and major surgery such as cystectomy
- Recent studies indicate an association between high-volume centers & improved post-op outcomes for major surgery
- Spurred interest in association of patient travel distance on cystectomy care and outcomes.



HOSPITAL VOLUME AND SURGICAL MORTALITY IN THE UNITED STATES

THE NEW ENGLAND

JOHN D. BHKNEYER, M.D., ANDREA E. SEWHER, M.P.H., EMILY V.A. FRLAYSON, M.D., THERSE A. STUGEI, PR.D.,

F. LEE LUCAS, PR.D., IDA BATISTA, B.A., H. GLERT WELOY, M.D., M.P.H., AND DAVID E. WINNERS, M.D., M.P.H.

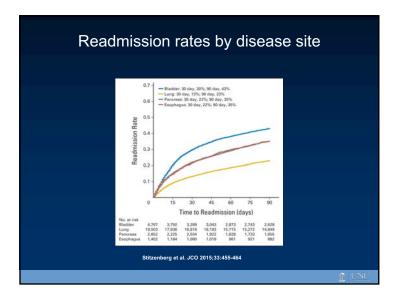
# Background

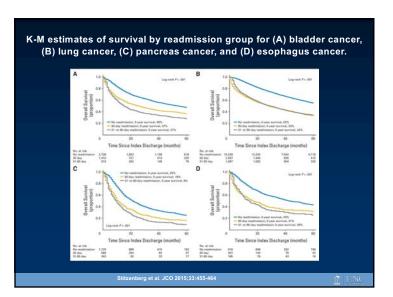
- 90-day complication rate = 64 78%
- Population-based estimates of readmissions following cystectomy range from 25-43%





MARTIN NUTTALL,\* JAN TAN THE MELLEN, NERREE PHILLIPS, CARLOS DAVID GILLATT, GREGOR M-INTOSH AND MARK EMBERTON





# Background

- 30% of bladder cancer re-admissions are to a different hospital
  - More likely later, lower socioeconomic status, through the ED, and for medical DRGs
  - Decreased survival (HR 1.35)
  - Only 8% transferred majority to index hospital
- The relationship between distanced traveled for surgery and risk of readmission and complications remains unclear

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### Question

How does distance traveled for surgery affects risk of readmissions and other outcomes following radical cystectomy for bladder cancer.



### Methods

- Using linked data resource combining North Carolina Cancer Registry with administrative claims data from Medicare, Medicaid, and private insurance
  - Integrated Cancer Information and Surveillance System (ICISS)
- Included adult patients diagnosed with bladder cancer from 2003–2010 who received RC.
- Complications coded and grouped based on previously published standards\*
- Travel distances calculated using straight-line distance between patient zip code & cystectomy provider

\* Konety et al., Birkmeyer et al., Hollenbeck et al.

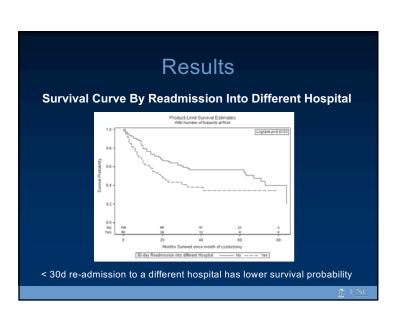


### Results

- 735 cystectomy patients for bladder ca.
  - n = 171 (23%) readmitted within 30 days
  - n = 156 (21%) readmitted between 31-90 days
- Mean age higher among readmitted, but not statistically significant
- No significant differences in readmission
  - race, gender, pathology stage, neoadjuvant chemotherapy, discharge to SNF comorbidity status, or complication type.

Results				
Distance & 30-day readmission at different hospital				
Characteristic		•	Imission into Hospital	P-Value
	Total (N = 171)	No (N = 107)	Yes (N = 64)	
Distance <= 30 miles	75 (44%)	56 (52%)	19 (30%)	0.004
Distance > 30 miles	95 (56%)	51 (48%)	45 (70%)	0.004
Distance & 3	Distance & 31-90-day readmission at different hospital			
Characteristic			admission into Hospital	P-Value
	Total (N = 156)	No (N = 80)	Yes (N = 76)	
Distance <= 30 miles	77 (49%)	53 (66%)	24 (32%)	<0.001
Distance > 30 miles	79 (51%)	27 (34%)	52 (68%)	<b>\0.001</b>

Multivariable Analysis: Predictors of 30-day readmission				
Variable		Odds Ratio	95% CI	p-value
Distance between residence & cystectomy provider (Ref <=30mi)	>30 miles	1.27	1.05, 1.54	0.014
Gender (Ref = Male)	Female	0.96	0.76, 1.20	0.707
Race (Ref = Non-white)	White	1.17	0.81, 1.67	0.402
Age (Ref = 65-74)	19-64	1.05	0.72, 1.54	0.798
Age (Rei = 05-74)	75+	1.06	0.78, 1.43	0.706
	Ta-Tis-Tx	0.88	0.62, 1.25	0.480
Pathologic Stage (Ref = T0-T2)	T3-T4	0.98	0.70, 1.37	0.892
	Missing	1.02	0.62, 1.68	0.931
Major complication	Yes	0.89	0.73, 1.08	0.245
Distance to SNF	Yes	0.74	0.50, 1.08	0.116
Imaging during Initial Hospitalization	Yes	1.05	0.77, 1.42	0.769
Neoadjuvant chemotherapy	Yes	1.35	0.93, 1.97	0.114
Length of stay < = 7 days	Yes	0.91	0.73, 1.13	0.394
Comorbidity (Ref = 0)	1	1.16	0.94, 1.43	0.180
Cornorbidity (Ref = 0)	>=2	0.98	0.68, 1.41	0.924
Insurance type (Ref = Medicare)	Private	0.97	0.68, 1.39	0.870
insurance type (Ref = Medicale)	Medicaid	1.06	0.69, 1.64	0.788



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# Conclusions

- Longer travel distance to a cystectomy provider is associated with higher 30-d readmission rates, readmission to a different hospital (closer to home), and worse survival
- Travel distance may indeed be a barrier to high quality care

# Conclusions

- Patients with longer travel distance may benefit from shorter and more frequent follow-up via phone, virtual post-op check, and PCP visits.
- Highlights need for better care coordination between index hospital and surrounding hospitals



# **Future Directions**

- Identify and compare early and late postoperative complications.
- Explore reasons for underlying disparities between outside versus index hospitals – which can be managed by outside and which should be transferred

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# Obstacles to optimal healthcare delivery in bladder cancer

- Travel Distance
- Financial Toxicity
- Nutrition

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# The burden of cancer isn't just cancer By Carolyn Y. Johnson April 8 (Rachel Orr/The Washington Post)

# Introduction

- Financial Toxicity "an adverse financial condition as a consequence of medical treatment"
- Cancer patients are 2.7X more likely to declare bankruptcy than those without cancer (even higher for younger cancer patients).

Ramsey et al, Health Affairs (2013)

# **Financial Toxicity**

- 13 percent of non-elderly patients with cancer spend at least a fifth of their income on treatment.
- Medicare cancer patients spent an average of \$4,727 of their own money on health care -about \$1,000 more than people without cancer.

Davidoff et al, Cancer (2013)

Bernard et al, JCO (2011)



# **Financial Toxicity**

- Of the 20 million cancer survivors evaluated, 29 percent reported financial burden of some kind
  - Bankruptcy to borrowing money to not being able to pay for medical visits.
- Among those reporting FT, 86% <u>had</u> health insurance

Hrishikesh et al, Cancer (2014)



# **Financial Toxicity**

- Is FT a health issue does it affect QOL? Survival?
   Were people skipping doctor's visits, drugs or other treatments?
- A copay of \$50 a month kept nearly a fifth of patients from continuing to fill prescriptions for TKI therapy for CML.
- For oral TKIs, patients more likely to stop or delay drug therapy as the portion they paid increased.
  - 13-20% increase stopping/delaying use per \$10 increase in OOP costs

Dusetzina JCO (2014)

Kaisaeng et al, JMCP (2014)




# **Financial Toxicity**

- Half of insured cancer patients cut spending on food and clothing or dipped into savings to pay for their treatment.
  - Majority cut back on leisure activities
  - Three-quarters received financial assistance with their drug copayments.

Zafar et al, The Oncologist (2013)



# **Financial Toxicity**

- Cancer patients who declared bankruptcy are 1.8X likely to die (any cause) (HR = 1.79) than cancer patients who didn't declare
  - Highest for colorectal (HR= 2.47) and prostate (HR=2.07)
  - More likely to be younger, female, and non-white, to have local- or regional- (v distant-) stage disease at diagnosis
  - Mean age was 53.0 years, men (54%), mean income \$49,000, and white (86%), married (60%), and urban (91%) and had local- or regional-stage disease at diagnosis (84%)

Ramsey et al, JCO (2016)

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# Financial Toxicity and Bladder Cancer

- GU malignancies require expensive treatments and long-term surveillance
- Bladder cancer is estimated to be the most expensive cancer from diagnosis to death
- The effect of Financial Toxicity on GU malignancies has not been well defined

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# Methodology

- UNC Health Registry/Cancer Survivorship Cohort
- 144 bladder cancer patients enrolled; 138 completed baseline questionnaire
- Patients surveyed via phone within 2 weeks of enrollment



# Methodology

- Financial Toxicity (FT) defined as agreement with the statement "you have to pay more for medical care than you can afford" via PSQ - 18
- HR-QOL measured using FACT-G, FACT-BI and PROMIS questionnaires

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# Patient Demographic Characteristics

		N = 138 (%)		
	<56	22 (15.9%)		
Age (years)	56-72	68 (49.3%)		
	>72	48 (34.8%)		
Gender	Female	34 (24.6%)		
Gender	Male	104 (75.4%)		
	Black	14 (10.1%)		
Race	Hispanic	1 (0.7%)		
	White	123 (89.1%)		
Bladder Cancer Clinical T Stage	Non-invasive (Tis, Ta, T1)	69 (51.1%)		
	Invasive (T2-T4)	66 (48.9%)		
Financial Toxicity	Yes	33 (24%)		
i manciar toxicity	No	105 (76%)		



### Patient Characteristics and Financial Toxicity Financial toxicity No Financial toxicity N= (%) Overall N= (%) p-value <56 22 (15.9%) 10 (45.5%) 12 (54.5%) <.0001 Age (yrs) 47 (69.1%) 56-72 68 (49.3%) 21 (30.9%) >72 48 (34.8%) 2 (4.2%) 46 (95.8%) Female 34 (24.6%) 8 (23.5%) 26 (76.5%) Gender Male 104 (75.4%) 25 (24.0%) 79 (76.0%) Black 14 (10.1%) 8 (57.1%) 6 (42.9%) 0.005 Race Hispanic 1 (0.7%) 0 (0.0%) 1 (100.0%) White 123 (89.1%) 25 (20.3%) 98 (79.7%) 0.554 <18.5 0 (0.0%) 0 (0.0%) 0 (0.0%) 18.5-24.9 41 (29.7%) 8 (19.5%) 33 (80.5%) BMI (kg/m²) 25-29.9 52 (37.7%) 11 (21.2%) 41 (78.8%) 24 (17.4%) 30-34.9 8 (33.3%) 16 (66.7%) >35 21 (15.2%) 6 (28.6%) 15 (71.4%)

		Overall	Financial toxicity	No Financial toxicity	p-value
	Single	14 (10.2%)	3 (21.4%)	11 (78.6%)	0.949
	Married/Living with partner	95 (69.3%)	22 (23.2%)	73 (76.8%)	
	Divorced/Separated/ Widowed	28 (20.4%)	7 (25.0%)	21 (75.0%)	
	Eighth grade or less	4 (2.9%)	1 (25.0%)	3 (75.0%)	0.014
	Some high school	9 (6.5%)	4 (44.4%)	5 (55.6%)	
	High school degree/GED	45 (32.6%)	13 (28.9%)	32 (71.1%)	
	Some college or Technical school	33 (23.9%)	11 (33.3%)	22 (66.7%)	
	Some graduate/masters	28 (20.3%)	4 (14.3%)	24 (85.7%)	
	Completed postgraduate/ Professional	19 (13.8%)	0 (0.0%)	19 (100.0%)	
Bladder Cancer Clinical T	Non-invasive (Tis, Ta, T1)	69 (51.1%)	48 (69.6%)	21 (30.4%)	0.042
	Invasive (T2-T4)	66 (48.9%)	56 (84.8%)	10 (15.2%)	

Patient Qu	ality of I	Life and Fina	ncial Toxicit	ty					
	Overall Mean (SD)	Financial toxicity, Mean (SD)	No Financial toxicity, Mean (SD)	p-value					
FACT-GP <sup>1</sup> , Total score	79.4 (18.3)	72.2 (21.4)	81.5 (16.7)	0.01					
FACT-GP <sup>1</sup> , Physical well being	22.3 (5.3)	20.3 (5.7)	23.0 (5.0)	0.01					
FACT-GP <sup>1</sup> , Social/family well being	20.6 (5.8)	19.2 (6.6)	21.1 (5.5)	0.11					
FACT-GP <sup>1</sup> , Emotional well being	19.2 (5.0)	18.3 (5.3)	19.5 (4.9)	0.21					
FACT-GP <sup>1</sup> , Functional well being	17.1 (8.0)	14.6 (9.2)	17.8 (7.5)	0.05					
FACT-BL <sup>2</sup> , Bladder cancer specific	33.3 (6.6)	32.4 (7.5)	33.5 (6.3)	0.41					
PROMIS <sup>3</sup> Global Physical Health T-Score	46.4 (9.8)	43.2 (11.2)	47.4 (9.2)	0.03					
PROMIS <sup>3</sup> Global Mental Health T-Score	49.9 (9.7)	45.5 (10.0)	51.3 (9.3)	<0.01					
	FACT-GP: Functional Assessment of Cancer Therapy- General Population  FACT-BL: Functional Assessment of Cancer Therapy- Bladder Cancer								

³Patient-Reported Outcomes Measurement Information System

# Observations

- 24% of bladder cancer patients endorsed FT
- Younger patients more likely to experience FT; may be related to Medicare Eligibility
- Increased prevalence of FT among
  - African Americans
  - those with less education

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# Observations

- Higher rates of FT among patients with noninvasive disease
  - Frequency and length of surveillance
  - Expensive surveillance procedures
- FT negatively associated with physical, functional and mental health-related QoL

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# **Next Steps**

- Does FT effect healthcare adherence?
- · Does FT have an effect of mortality?
- When and how does FT develop?
- What is the prevalence of FT in other GU malignances?
- What strategies can be put in place to limit the development of FT?

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# What are the obstacles to optimal healthcare delivery in bladder cancer? Travel Distance Financial Toxicity Nutrition **Nutritional Deficiency** • Inadequacy of nutrients in tissues; result of inadequate dietary intake or impairment of digestion, absorption, transport, or metabolism. **Nutritional Deficiency** • Elderly at increased risk for nutritional deficiency

- - Mean age of bladder cancer patient = 73 years
- 40-80% of cancer patients are Nutritionally Deficient
- · Elderly cancer patient are at particularly high risk

### **Anecdotal Case**

- 70 year-old male presented with bladder cancer
- · Complaints of "bad taste" and weight loss in preceding months before surgery (cystectomy)
- · Postoperative course was complicated wound problems, readmission, prolonged stay, and need for IV nutrition (TPN)

Could this have been prevented by a preoperative evaluation and intervention?



# **Nutrition & Surgery**

- Nutritional deficiency is a well-known risk factor for complications in surgery patients
  - Infections
  - Poor wound healing
  - Mortality
  - Decreased overall survival
- Several studies have demonstrated correlation between malnutrition and high clinical and economic effect
  - Increased morbidity
  - Prolonged hospital stay
  - Substantial increased cost of healthcare
  - Increased mortality



# **Urology & Nutrition**

- · Urologic surgery represents an exceptional position in surgery
- · Many patients who undergo a major procedure a 70 years
- Using NRS-2002 tool, patients ≥70 who undergo major surgery will have a score ≥3 (at risk of malnutrition), independent of other factors.
- Malignancy is another risk factor

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# Terry & Bueschen, 1986

- Retrospective review of 69 radical cystectomies
- Preop nutritional status assessed by WBC & serum albumin
- 75% with severe nutritional depletion had severe complications

COMPLICATIONS OF RADICAL CYSTECTOMY AND CORRELATION WITH NUTRITIONAL ASSESSMENT

WILLIAM J. TERRY, M.D. ANTON J. BUESCHEN, M.D.

From the Division of Urology, Department of Surgery, University of Alabama at Birmingham, Birmingham, Alabama

# **Recent Studies**

- 2011 (Gregg et al)

  - 103 of 538 (19%) met criteria for ND
    90-day mortality 16% ND vs. 5% non-ND
    Overall survival at 3 years was 44% for ND vs. 68% for non-ND
- 2013 (Johnson et al)
  - Analysis of 1092 cystectomy patients in NSQIP
  - Low albumin was strongest predictor of complications
- 2014 (Smith et al)
  - Sarcopenia (muscle wasting) measured on CT scan
  - Predictor of complications and trend towards 2-yr survival



# **Assessment of Nutritional Statu**

- · Not straightforward
- No standardized definition of nutritional depletion
- · Traditional markers of nutritional status
  - Weight
  - Serum albumin
  - Pre-albumin
  - CRP
  - Immune competence
  - Appetite, GI symptoms, energy level, loss of SQ fat, musc wasting, edema, ascites
  - Hand-grip strength
  - Nutritional Indices

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# **Nutrition Markers**

- · Ideally should consider multiple factors:
  - Patient's physiologic requirements
  - Nutritional intake
  - Functional Status
  - Body composition



### · Ideal nutritional marker:

- Sensitive enough to identify alterations in early stage
- Specific enough to modify only due nutritional imbalances
- A nutritional intervention would correct its alteration
- Correction of its levels would result in a better outcome



# **Albumin**

- Albumin
  - Hepatic protein, 60% of plasma proteins
  - 20-day half-life marker of chronic malnourishment
  - Negative acute phase reactant

### • Hypoalbuminemia – non-specific

- Liver disease, nephrotic syndrome, burns, proteinlosing enteropathy, malignancy, malnutrition
- May be better surrogate of disease state

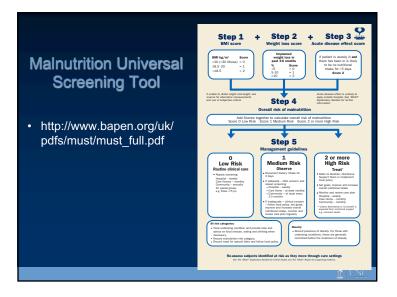


# **Nutritional Indices**



- Absence of a single gold standard objective measure has led to nutritional indices
  - Nutritional Risk Index & Maastricht Index
  - Mini Nutritional Assessment
  - Malnutrition Universal Screening Tool
  - Nutritional Risk Index-2002
  - Patient-Generated Subjective Global Assessment (PG-SGA)

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I. Weight (See Worksheer I)  In summary of my current and recent wei  Leurrently weigh about pounds  feet	pounds pounds pounds secreased Box 1	2. Food Intake: As compared to my anomal intake, I would nate my food intake during the past mouth as:    unchanged,
cating enough during the past two weeks ( no problems cating , no problems cating , no problems cating , no no protein, just did not feel like eating nausea , constitution , mouth sores , things tasse funny or have no taste , problems wallowing , pain, where? ,  ** Examples: depression, money, or de	overniting as of diarrhea as of feel full quickly as of fatigue as	would generally rate my activity as:  ground with no limitations; ground with no limitations; ground with no limitations; ground with no limitations; ground with lairly normal self, but albe to be up and about with fairly normal activities; ground feeling up to most things, but in bed or chair less than half the da grate be to do little activity and spend most of the day in bed or chair; greetly much bedridden, rarely out of bed.

Worksheet 1 - Scoring V				t-Gen	nerated Subjective G							10 F	7.4
To determine score, use I menth weight data if available. Use 6 month data only if there is no 1 month weight data. Use points below to score weight change and add one extra point if protent has been weight during the past 2				Additive Score of the Boxes 1-4 (See Sode 1) A  5. Worksheet 2- Disease and its relation to nutritional requirements									
				past 2	All relevant diagnoses (specify)								
We foss in I mouth Points We foss in 0 months 10% or greater 4 50, 97% 3 34.49% 2 6 9.97% 2.27% 1 2 5.57% 0.1.9% 0 0 1.0%					Cine point each:    Cineter   AIDS   Pulmonary or cardiac cachesia   Presence of deculatins, open wound, or fish   Presence of trauma   Age greater than 65 years   Chronic renal insufficiency					or fistul			
Numerical score	from W	orksh	ret 1					Num	erical s	core from	n Workshee	12	B
6. Work Sheet 3 - Metab	olic Den	band											
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# Interventions: Role of Patient and Referring MD

- · Arguably play the most important role in nutrition
- Provides the largest window between diagnosis and surgical therapy
- Nutrition optimization needs to begin at time of diagnosis to provide the most impact

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# **Nutrition Supplementation**

- Encourage nutrition supplementation
  - Boost
  - Ensure
- Daily multivitamin
- Referral to dietitian/nutritionist
- Exercise program



# A quick word about other preoperative factors...

- Smoking cessation
- Weight loss in obese patients
- Exercise/Prehab



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# **UNC Cystectomy Nutrition Protocol**

# <u>Visit 1 – at initial consultation in MDC (+ FU at time of preop if NAC)</u>

- · All patients seen by RD in adjoining clinic
- Patient-Generated Subjective Global Assessment (PG-SGA)
- Labs (at visit and repeat at pre-op)
  - Prealbumin
  - CRP
  - Albumin



# **UNC Cystectomy Nutrition Protocol**

### Visit 1 (cont'd)

- · Preoperative diet optimization & possible carb loading
  - e.g
    - Prealbumin <18mg/dL → check nitrogen balance preop, increase protein to >1.5 gm/kg/d
    - If prealbumin is <18mg/dL with negative nitrogen balance, increase protein to 1.8-2gm/kg/d
    - Recheck in 2-3 weeks
- Receive nutrition packet with individual protein recommendations, meal plans, protein lists, protein loading,



# **UNC Cystectomy Nutrition Protocol**

### Visit 2 – In-patient after cystectomy

- RD consult on POD #3
- Reiterate home recommendations & decide on improvements for nutrition
- Multivitamin use (i.e. zinc deficiency relates to possible taste alterations?)

### Visit 3 - Post-operative Visit (2-3 weeks postop)

Further review of recommendations and improvements

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# **UNC Cystectomy Nutrition Protocol**

### Visit 4 – Post-operative FU (3 months) (optional)

- Repeat ND assessment
- Further review of recommendations and improvements
- Labs
  - Prealbumin
  - CRP
  - Albumin



# Conclusion

- Malnutrition is an important risk factor for all patients undergoing urologic surgery
- Multiple nutrition assessment indices exist
   PG-SGA
- Further nutrition studies are needed identify malnutrition and best source of nutrition
- · Need to identify and intervene early
  - Diet, exercise, other health-related behaviors



# Radical Cystectomy: 2019

- Refining Multimodal Therapy
  - Improving utilization of perioperative chemo
  - Development of new agents
- Innovation to improve peri-operative Outcomes
  - Clinical care pathways
  - Refining the role of Robotics
  - Overcoming obstacles to optimal care

# **Improving Outcomes**

- Increasing number of patients with invasive / advanced disease
  - Aging population = more bladder cancer
  - Referral practices: ad hoc regionalization
  - Reimbursement environment: QI
- Need for Innovation in the treatment of bladder cancer patients to improve outcomes



# Future Directions

- Optimizing patient
  - Nutrition
  - Pre-hab
- Better care coordination (role of travel distance)
- Financial toxicity
- mHealth



# At home PROs

- · Structured patient phone calls by APP
  - question categories: symptoms, emotional/social, functional assessment.
  - Weekly < 30 days; bi-weekly 30-90 days
- · Reduced ER visits and re-admissions
- High patient satisfaction
- Improved communication

Smith et al (2017)

# mHealth

- · Address preventable complications / readmissions Use of HIT - e.g. mobile health (mHealth)
- · Tracks PROs and allows real-time feedback via internet-enabled devices





# mHealth

- · Patient-centered care
- · Increase quality
- Timely intervention of complications (UTIs, dehydration, fevers)
- High patient satisfaction
- Reduce morbidity, healthcare utilization (costs/penalties), death



# **Improving Outcomes**

- · Increasing number of patients with invasive / advance disease
  - Aging population = more bladder cancer
  - Referral practices: ad hoc regionalization
  - Reimbursement environment: QI
- · Need for Innovation in the treatment of bladder canc patients to improve outcomes

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"The fundamental problem with the quality of American medicine is that we've failed to view delivery of health care as a science."

- Peter Pronovost MD

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