PERSPECTIVES IN UROLOGY POINT COUNTERPOINT 2009

Thursday, November 5, 2009 Ballroom E-F The Scottsdale Plaza Scottsdale, Arizona



Wednesday, November 4

6:00 – 8:00 pm Registration

Thursday, Nover	mber 5	Page
7:00 – 7:55 am	Registration and Continental Breakfast in Exhibit Hall	
7:55 – 8:00 am	Welcome and Introduction	
	~ E. David Crawford, MD	
Robotic Surgery		
8:00 – 8:30 am	The Role of Robotics in Urologic Surgery	1.3
	~ Paul D. Maroni, MD	
8:30 – 9:00 am	Point-Counterpoint: Prostate Cancer	2.1
	Robotic Surgery is Hype ~ E. David Crawford, MD	2.1
	Robotic Surgery is the Mainstream ~ Paul D. Maroni, MD	2.16
9:00 – 9:10 am	Questions & Answers	
Renal Cell Carcinoma		
9:10 – 9:30 am	Histologic Subtypes of Renal Cell Carcinoma	3.1
	~ M. Scott Lucia, MD	
9:30 – 9:55 am	Point-Counterpoint: Small Renal Masses	4.1
	Best to Remove ~ Paul D. Maroni, MD	4.1
	Best to Watch ~ Donald L. Lamm, MD	4.2
9:55 – 10:00 am	Questions & Answers	
10:00 – 10:15 am	Break in Exhibit Hall	
Female Urology, Part I		
10:15 – 11:15 am	Female Urology "Potpourri"	5.1
	~ Brian J. Flynn, MD	
11:15 – 11:25 am	Questions & Answers	
Clinical Challenges		
11:25 – Noon	Case Presentations and Discussion	
Noon	Adjourn for the day	

The Role of Robotics in Urologic Surgery

~ Paul D. Maroni, MD

The Role of Robotics in **Urologic Surgery**



Objectives

- Review history of robotics in surgery/urology
- Identify areas where robotic surgery can be useful.
- Avoid pitfalls of robotic surgery.
- Learn a responsible way to integrate into your practice.

Brief history of robotic surgery

- "robot" coined by Karel Capek in 1921 from Czech word robota meaning forced labor
- 1985 PUMA 560 used for brain biopsy
- 1987 first robotic gall bladder removal
- 1988 PROBOT for TURP
- Late 1980s ROBODOC first FDA approved for hip surgery
- Late 1980s NASA and US Army developed systems

The Role of Robotics in	
Urologic Surgery	
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Paul D. Maroni, MD	
Assistant Professor	
Department of Surgery/Urology	
University of Colorado at Denver	

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I LIISI LCTIVES IN UNOLUGI, PUINT- COUNTERPO	DINT • November 5–7, 2009 • The Scottsdale Plaza • Scottsdale, Arizona

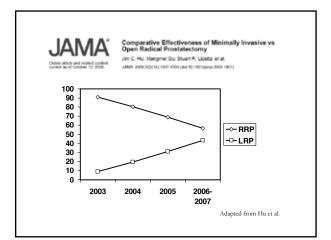
Brief history of robotic surgery

- 1993 AESOP approved for surgery
- 1997 daVinci begins use
- 1998 ZEUS first fully robotic surgery

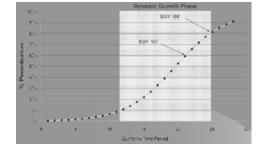
(Computer Motion)



- 2000 daVinci approved by FDA (Intuitive Surgical, Inc)
- 2003 Computer Motion merged with Intuitive Surgical, Inc.

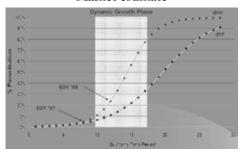


Adoption of robotic prostatectomy Market estimate





Adoption of robotic hysterectomy Market estimate



Gold or Bubble Gum

- Winners
- Losers
- Early adopters
- Late/non adopters
- Intuitive Surgical,
- Healthcare system
- Inc./ stockholders
- Early patients
- Late patients (?)

How are late patients helped?

- Forced most prostate surgeons to improve results/technique
- Regionalization

or

 Identify processes of care in high volume hospitals and implement at lower volume centers

Robotic procedures in Urology

- Radical prostatectomy
- Nephrectomy/partial
- Pyeloplasty
- Ureteral reimplant
- Cystectomy
- Adrenalectomy
- Simple prostatectomy
- Bladder diverticulectomy
- Urinary diversion
- Pelvic lymph node dissection
- RPLND
- Inguinal lymph node dissection

Lap versus robotic

- Would you close one eye while operating? NO
 - 3-dimensional view with robot
- Would you lock your wrists? NO
 - Wristed instrumentation with robot
- Would you prefer to move more precisely? YES
 - Motion scaling and tremor filtering with robot
- Would you rather be comfortable? YES
 - Ergonomic seated position with robot
- Would you prefer to be cost effective? YES
 - Don't use the robot for things safely done laparoscopically

Robotic assisted partial nephrectomy

- AUA Guidelines
- "... only a few small, single-institution reports offer limited information regarding this procedure, including whether robotic-assisted LPN offers any advantages over other forms of nephron-sparing surgery (NSS). At present there are insufficient data to evaluate outcomes."

Guideline for Management of the Clinical Stage 1 Renal Mass. AUA 2009

Healthy, clinical T1a enhancing renal mass

 Standard: Complete surgical excision by partial nephrectomy is a standard of care and should be strongly considered.

Both open and laparoscopic approaches to PN can be considered... LPN can provide more rapid recovery, although this approach has been associated with increased warm ischemic times and an increased risk of urological complications including postoperative hemorrhage and urinary fistula... a solitary kidney, preexisting renal dysfunction, hilar tumor, multiple tumors or predominantly cystic tumor are best managed with an open surgical technique. With improved laparoscopic instrumentation and greater dissemination of expertise, improved outcomes and more widespread application of LPN is anticipated in the future.

Guideline for Management of the Clinical Stage 1 Renal Mass. AUA 2009

Robot Assisted Partial Nephrectomy Versus Laparoscopic Partial Nephrectomy for Renal Tumors: A Multi-Institutional Analysis of Perioperative Outcomes

Brian M. Bensuy,* Sam B. Bhayani,† Craig G. Rogers,† Lori M. Dalabon, Manish N. Patel, Michael Liptin, Agnes J. Wang and Michael D. Sütelman?

J Urol September 2009

- 118 LPN, 129 RAPN 3 surgeons
- No difference in OR time or positive margin rate (3.9% v. 1%)
- Less blood loss and warm ischemia time for RAPN (19.7 min v. 28.4 min)
- Similar post-op complications (10.2% v. 8.6%)
- Long-term oncologic outcomes unknown

My opinion RAPN

■ Still a difficult operation for the novice roboticist

ated with a learning curve. Unlike robotic pyeloplasty and prostatectomy, robotic partial nephrectomy places a time constraint upon the surgeon because of the need to minimize warm ischemia time [17*].

■ Little information on learning curve, but probably not as shallow as LPN

Shapiro et al Curr Opin Urol 2009

Robotic assisted radical nephrectomy/nephroureterectomy

- No literature on RARN
- Probably no different than LRN

Robotic assisted Ureteral Surgery: Pyeloplasty

	Patients	ORtime (min)	Comps. (%)	Success (%)	F/U (mo)
Palese	35	216	11	94	7.9
Gettman	9	138	11	100	4.1
Siddiq	26	245	12	95	6
Schwent ner	92	108	4	97	39.1
Patel	50	122	nil	96	11.7

Adapted Leveilee and Williams Curr Opin Urol 2009

Robotic assisted Ureteral Surgery: Ureteral reimplant

- Limited publications on this subject
- Leveillee and Williams Curr Opin Urol 2009
 - \blacksquare 8 patients with benign diseases
 - Mean follow-up 18 months
 - 1 recurrence treated sucessfully with balloon dilation
 - Psoas hitch and Boari flap still available

Opinion:

Will probably become widely accepted for benign and malignant disease (oncologic results unknown – Glinianski et al J Endourol 2009)

Robotic assisted Cystectomy

- Around 300 cases published (size 1 to 67 patients)
- Complications (10-30%
 - data largely incomplete
- Avg blood loss <300 ml
- Avg OR time ~ 7 hours
- Oncologic data remains to be seen

Hemal Curr Opin Urol 2009

Robotic assisted cystectomy Questions

- Will it decrease hospital stay? Complications?
- Can the OR times be shortened?
- Can an equivalent LND be done?
- How to handle the urinary diversion?
- Oncologic outcomes?

Opinion:

Long way to go. Probably good for benign disease.

Robotic assisted urinary diversion

- Intracorporeal ileal conduit and orthotopic bladder substitution have been done
 - OR time >10 hours
- Most make 8 cm incision to remove specimen and create urinary diversion.

Hemal Curr Opin Urol 2009

Robotic assisted adrenalectomy

- Case series and a few comparison studies (1 RT)
- About 150 patients published
- Complications inconsistently published
- Most metrics similar to lap adrenalectomy
- Longer OR time and more expensive for robot
- "subjective improvement" with robot
- Use in malignant disease TBD

Hyams and Stifelman Curr Opin Urol 2009

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Robotic assisted simple prostatectomy

- Technically feasible
- Case series x 2, 3 and 7 patients
- Millin's technique
- Modest EBL <600, 300 respectively
- 3-4 hours!!!

Opinion

Learn HoLEP. Probably not for robot.

Sotelo et al J Urol 2008, Yuh et al Can J Urol 2008

Robotic assisted bladder diverticulectomy

- Little in literature
- Easy to do robotically
- Curl guidewire in diverticulum
- Unproven for cancer
- Can do PVP simultaneously

Opinion

Excellent training case. Quick and handles all comers. Not for malignancy yet.

- Pelvic
 - Well described and can do extended lymph node
- RPLND
 - Only 2 patients in PubMed
 - Expect more will come
- Inguinal LND
 - Believe it or not (Josephson et al Urology 2009)
 - Leave this to the few
- Commercial
 - Caveat emptor
 - Equal relationship
 - Self-interest

Medical reality

 Practical constraints to practicing physician taking significant amount of time to learn new procedures.

Old credentialing process

- "Hey, do you want to use the robot?"
- Off-site training certificate and proctoring paid for by industry.

Or

■ Letter from program director.

Gold Rush aka - The learning curve

- 2 of first 10 patients at place I did fellowship had rectourethral fistula after prostatectomy
- Bad complications common
 - Urinary leaks
 - Incomplete prostate removal
- Promises not delivered
 - More incontinence and impotence

University of Colorado Hospital Robotic Credentialing

- Ongoing QI processes and M and M
- 1. Training pathway
 - Significant residency or fellowship experience
 - 3 proctored cases
 - Period of observation (10 cases)
- 2. Practice pathway
 - Device training online, off-site certificate
 - 3 proctored cases
 - Period of observation (17 cases)
 - CME or advanced course

•	CME	or	advanced	cours

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University of Colorado Hospital Robotic Credentialing

- 3. Experience pathway
 - 20 cases as surgeon and 10 within last year.
 - List of complications
 - Verification of robotic privileges at other medical center
 - Supportive letter of recommendation from Chair of Surgery/Department.

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- Fellowship
 - 6 months to 3 years
 - Hands-on required
- Mini-fellowships
- Self-directed
 - Dry-lab
 - Courses hand-on and video observation

Prerequisites

- Experience with laparoscopy
- Understand an investment is necessary
- Discuss with partners (if any)
- Willingness to start slowly

How to incorporate

- Case observation
- Video observation
- Basic training
 - Online module
 - Hands-on off-site certification
- Dry-lab time (very helpful!)
- Honesty is the best policy/dispel myths/expectations
- Start with simpler procedures soon after training
 - Nephrectomy
 - Bladder diverticulectomy

How to incorporate

- Find reputable and experienced proctor for 3-5 cases
 - Case is a failure if the proctor needs to do significant/important portions
- More dry lab
- Get help for first few cases on your own
- Advanced course after 10-15 cases
- Work into more complicated procedures slowly
- Continue to participate in courses

Tips to minimize complications/facilitate procedure

- Well-prepared team (good assistant important)
- Always keep hands in view
- Center hands every few minutes (minimizes need to clutch)
- Foot positioned by camera pedal
- Let hands lead the way
- Constant back and forth when suturing
- Blink

Technical improvement

- Record results
 - Use easy questionnaire
- Record procedures
- Investigate causes of positive margin
- Ongoing review of literature, techniques, courses

Point-Counterpoint: Robotic Surgery

Prostate Cancer Robotic Surgery is Hype ~ E. David Crawford, MD Robotic Surgery is the Mainstream ~ Paul D. Maroni, MD

Robotic prostatectomy? HYPE

E. David Crawford, MD Professor of Surgery (Urology) and Radiation Oncology University of Colorado Health Sciences Center

ARS

Do you believe that the robot has significantly improved the care of patients undergoing a radical prostatectomy

1. yes

2. no

Just because you have a Ferrari does not make you a race car driver



Robot and LPR Primary Advantages

- Faster recovery no lower abdominal incision
- Less blood loss pneumoperitoneum
- · Better preservation of the NVB magnification
- · Better Vesicourethral anastomosis direct vision

Robot

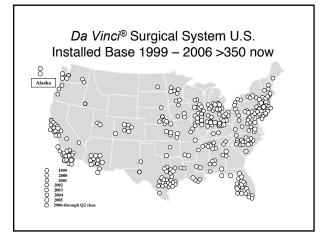
- · Supposed improvement over lap
- · 3-D up-close
- · Wristed motions
- · Tremor and movement scaling

Conclusions

- · A lot of marketing hype
- Skill trumps any technique Robot=RRP=RPP=Lap RRP There is no difference in any parameter with the robot (even blood loss)
- · To much time wasted at meetings
- · Has done nothing to advance care

Marketing

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Boston Globe -continued

 "It's unbelievable how good it was," said Philip Bedard, 59, a Boxford construction company "In five days I was back in the office, and in 10 days I was operating a backhoe."

The result - if a hospital does not have a robot you loose market share, even if not cost effective

Prostate Cancer Surgery

Google: Prostate Cancer Treatment

www.rcog.com	Comprehensive info from a world leader in treatment and research Prostate Cancer Surgery
www.laprp.com	America's longest running program for lap prostate cancer surgery Prostatectomy
www.CityofHope .com	Leading Treatment options including Robotic-Assisted Cancer Surgery

Do an internet search for prostate cancer:

Web I CNN News I CNN Videos Web results for "prostate caner" I Results 1-10 of 3,970 Sponsored Links Prostate Health

www.ProstateCare.com Important Information About
Determining Your Prostate Health. Robotic prostate surgery

www.StJosephsAtlanta.org Minimally invasive robotic surgery Saint Joseph's Hospital in Atlanta.

St Joseph's program

f da Vinci robotic surgery for prostate cancer has become the gold standard for treating prostate cancer has become the gold standard for treating prostate cancer.

Benefits of robotic surgery - Discover the many benefits of robotic surgery over traditional open surgery.

Neurovascular Plexus (NVP) robotic surgery procedure - Saint Joseph's physicians perform a special nerve-sparing that results in better long term outcomes.

What to expect - Browse frequently asked questions about robotic surgery for prostate can

Clinical references for robotic surgery - Read up on the latest robotic prostate surgery research and clinical outcomes.

Dr Shah in the video- used to be hard to recommend RRP - high rates of impotence, incontinence and bleeding, radiation, robot better results



Marketing-not on these websites

- · Canadian Study-CUAJ June 2007, 1(2), 97
- · Initial cases
- · + margins-30%
- 10-20% SUI
- · Post op 3.5 days
- · 12 days catheter
- 50 cases a year/high volume centers
- · Recommend limiting to 5-10, high volume

Marketing-not on websites

- Borden-CJU, 14(2)3400. 2007
- Seattle 350 cases-2.6% device malfunction
- 6 aborted
- · 3 lap or open
- Malfunction -psychologic,financial, logistical burdens

Marketing

- · You will be left out
- · Hospital against hospital
- · Mid size cities where there are 5 robots
- · Hospitals loose money
- When is the last time you were detailed on a perineal prostatectomy?

'The ideal way to compare Robot,LPR, RRP,RRP is a randomized clinical study using common clinical pathways'

In 2009

A man undergoing open RRP can expect:

- · Uncomplicated surgical procedure
- · A short and uneventful hospital stay
- · The lack of allogeneic blood transfusion
- · Early removal of the urinary catheter
- · Full return to activity within 3 weeks
- · Restoration of urinary continence within 3 weeks

Only long term problem is ED

Shekarriz et al Urol Clin North Am

Outcomes After Radical Prostatectomy: Ranked Order Based on Clinical Importance

- Cancer control
- · Technical complications
- Postoperative complications
- Urinary continence
- Erectile function
- Cost
- · Blood loss
- · Timing of catheter removal
- · Length of hospital stay
- Postoperative pain

The Surgeon Makes the Difference

Not the technique Robot, RRP, RPP, Lap

Operative time

- · Lap longer
- · Robot less
- RRP less
- · With experience all about the same

Blood loss

- · Lap and robot less
- But experience trumps all

Complications

- · No difference
- Perhaps more bladder neck contracture with lap/robot
- Disasters with Robot/Lap vascular injuries, rectal, anastomosis

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Hospital Stay

· No difference

Functional Outcomes

· No difference

Urinary Control

- AUA Abstract # 1605-Vanderbilt
- · Robot-320 90% 1 year
- RRP- 195 88% 1 year
- · No difference and this is what other series report, though not all at the same institution.
- · Patients are led to believe better

Center	Appr	No	Mean	Mean	Transfu	Mean	Complic	Positive
	oach	Pts	op time	EBL	sion %	LOS	ations	Surgical Margin
Rassweiler et al	TLRP	219 219	288 218	1100 800	30.1 9.6	12 11	19.6 10.5	21 23.7
Goeman et al ²⁰	TLRP	165	240	678	1.2	6.7	9.1	23
Eden et al23	TLRP	100	238.9	310.5	2	3.8	8	16
Guillonneau et al6	TLRP	550	200	380	5.3	5.8	10	15
Cathelineau et al ²¹	ELRP	600	173	380	1.2	6.3	11.5	17.7
Tuerk et al ²²	ELRP	174	169	176	0	1.67	9.9	14.5
Goeman et al ²⁰	ELRP	550	188	390	4.7	4.6	10.9	pT2 17.9 pT3 44.8 pT4 71.4
Eden et al ²³	ELRP	100	190.6	201.5	0	2.6	4	16
Stoltzenberg et al 19	ELRP	700	151	220	0.9	-	2.4	19.8
Menon et al 16	RAR P	1142	154	142	0	1.14	2.3	13
Patel et al 3	RAR P	200	141	75	0	1.1	2	10.5
Joseph et al 10	RAR P	325	130	196	0.09	-	9.8	13
Rassweiler et al ⁷	ORP	219	196	1550	55.7	16	35.6	28.7
Zincke et al ²⁴	ORP	3170	-	600- 1030	5-31	-	-	24
Lepor et al25	ORP	1000	1-	819	9.7	2.3	7	199

• The Scottsdale Plaza •	

Center	Techniq	No. pts	PSA Non - Recurrence	Urinary Continence	Potency
Rassweiler et	TLRP	438	94% (3 mos)	90.3% (12 mos),95.8% (18 mos)	Not reported
Guillonneau et al ⁶	ELRP	550	pT2a 92.3% (36 mos) pT2 b 86.3% (31 mos)	82.3% No pad (12 mos)	BNS 85% (spontaneous erections), 66% (intercourse)
Goeman et al	ELRP	550	pT2 89.7% (5 yr) pT3 58.6% (5 yr)	91% (24 mos)	BNS 64%, 78.%6 and 90.9% (12 & 24 mos) if pt< 60 years old
Stolzenberg et al ¹⁹	ELRP	700	Not r eported	92% complete (12 mos) 98% 1 pad or less	BNS 47.1% (6 mos)
Menon et al	RARP	1142	Overall: 97.7% (36 mos) Gleason 6 - 98.5% Glesson 7 - 95.4% Gleason 8 & 9 - 60.1%	95.2% 1 pad or less (12 mos) 84% no urine leak	Bilateral veil technique 93% (48 mos) BNS 70% intercourse at 5 yrs
Mikhail et al	RARP	100	Not reported	84% return to baseline function (12 mos) 89% subjective continence (12 mos)	80% return to baseline sexual function (12 mos)
Patel et al	RARP	200	95% (9.7 mos)	98% (12 mos)	Not reported
lose ph et al "Catalona et	ORP	325 1325	97% (6 mo)	96% no pad(6 mo) 93%	70% (6 mo) BNS 68% UNS 47%
Geary et al	ORP	458		80.1 % No pads 8.1% 1 -2 pads 6.6% 3 -5 pads 5.2% totally incontinent	
Leandri et al	ORP	620		95 % complete control	71% wi th NS

Complication Rates Associated With Radical Prostatectomy, According to Prospective Studies

	Open RRP	LRP	(%)
Complications	Lepor & Kaci N = 500	Guillonneau et al N = 567	Ruiz et al N = 330
Rectal injury	0	1.4	1.8
Ileocolonic injury	0	0.9	0
Rectal fistula	0	NR	NR
Ureteral injury	0.2	0.7	NR
Bladder injury	0	NR	NR
Nerve injury	0	0.5	NR
Vascular injury	0	0.5	0
Wound complication	on 0.2	0.7	1.5

Guillonneau et al J. Urol 2002;167: 51 Ruiz et al. Eur Urol 2004; 46: 50 Lepor et al. Urology 2004; 63:499

Complication Rates Associated With Radical Prostatectomy, According to Prospective Studies

	Open RRP	LRP (%)
Complications	Lepor & Kaci	Guillonneau et al	Ruiz et al
	N = 500	N = 567	N = 330
Urinoma	0	NR	NR NR
Myocardial infarct	ion 0.4	NR	NR
Pulmonary embolu	s 0	NR	NR
DVT	0.4	0.3	NR
CVA	0	NR	NR
Prolonged ileus	0.4	1	1.5
Lymphocele	0	0	0.3

Guillonneau et al J. Urol 2002;167: 51 Ruiz et al. Eur Urol 2004; 46: 50 Lepor et al. Urology 2004; 63:499

Positive Surgical	Margins Afte	r Radical	Prostatectomy

		Positive Margins (%)		
Institution	Patients, N	pf _a Disease	pT, Disease	Study Period
	1 1 1			
New York University	1000	2.9	33.2	3000-3005
Enome Hospital	n	7.3		1999-2001
Cleveland Clinic	152	7.4	29.6	1994-1996
tomy				
University of Heidelberg	408	9.7	37.1	1999-2002
Monteur's Institute	1000	15.5	31.1	1996-2002
Heavy Ford	100	. 1	40	3001-2002
Henri Mondor	330	15.3	46.3	2000-2002
Enume Hospital	85	7.8		1999-2001
	New York University Essente Hospital Cheeland Clinic toney University of Heidelberg Historium Indiana Heart Mondar	Institution N	Institution N	Institution N Disease Disease

incurrent studies at same institution.

Continence Rates After Radical Prostatectomy, According to Disease-Specific Self-Administered Quality-of-Life Instruments

		Continent	ce Assessment	
Author(s)	Institution	Patients, N	Continent" (%	
Open radical prostat	ectomy			
Lepor et al	New York University	580	98.5	
Wei et al	University of Michigan	482	97.7	
Young et al	Duke University	92	97.8	
Laparoscopic radical	prostatectomy			
Olsson et al	Henri Mondor	36	100	
Link et al	Johns Hopkins	122	93	

[&]quot;Minimum of 12 months follow-up.



OK so what are alternatives to Robot?

Lap RRP RPP Modify how you do your standard RRP

LAP RRP

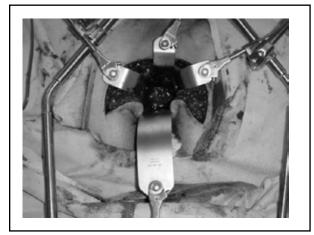
- Most European and many US Centers use Lap alone and have excellent results
 - Learning curve for suturing
 - Visualization

RPP RRP RALP



Introduction Radical Perineal prostatectomy

- 1904 Hugh Hampton Young
- 1947 Retropubic approach
- 1969 Jewett HJ \ Survival approaching
- 1982 Elder et al / age- matched population



Concerned about LN





Advantages of a Perineal Prostatectomy

- · Avoidance of an abdominal incision
- · Avoidance of blood transfusion
- Apical dissection is facilitated and margin rate decreased (7%)

Weldon et al. J Urol -1995

- Ease of anastomosis Watertight
- Early and immediate continence rates better Overall continence similar.

Weldon - J. Urol 1997, Bishoff - J. Urol 1998

Advantages of a Perineal Prostatectomy

- · Oral pain. No epidural or PCA
- Postoperative convalescence : Regular Diet Ambulation in 12 to 18 hours.
- · Discharge same day or next.
- Outpatient series only 12% wished >23 hr stay Ruiz-Deya et al. J urol. 2001.
- Prior surgery and obesity
- Potency: theoretical advantage due to better visualization but no clear evidence.
- WWW.medscape.com/viewarticle/551746

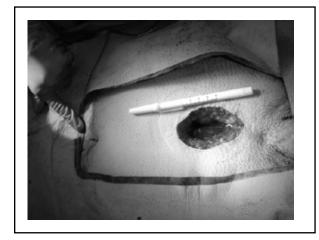
Perineal

Surgeon
Similar results as Robot, Lap,
RRP
Go home the same day

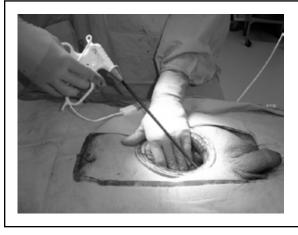
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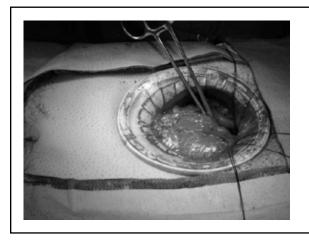
Anatomic Complete Prostatectomy



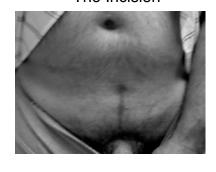








The Incision



From: Stacy Childs <stacyjchilds@yahoo.com>
Date: Wed, 20 Jun 2007 15:20:18 -0700 (PDT)
To: "E. David Crawford M.D." <edc@edavidcrawford.com>
Subject: "Your Patient"

Took his foley out today. Voids well, good sphincter control. He was driving at p.o. day #5, back at work at day #7. You're right, tiny incision. Impressive. Are you using all laparoscopic instruments and not fingers?

Stace

Stacy J. Childs, M. D. (970) 870-6684 hm (970) 871-9710 wk (970) 870-6698 fx hm (970) 871-9709 fx wk

Postoperative complications Last 400 cases

	Number of patients
Bladder Neck Contracture	27
Meatal stricture	7
Wound Infection	3
bladder neck stricture	2
Bladder infection	2
Rectal Tear	1
Penile Pain	1
Epididitymis	2
Hydronephrosis	1
Penile pain	1
Hydroureteronephrosis	1
Suprapubic postoperative hematomas	1
wound granuloma	1

2.	1	3

Demographics

Variable	Number	Mean (sd)	Median
Age	406	57.2 (7.1)	57.0
WM Gleason sum	373	6.5 (1.05)	7.0
Preoperative PSA (ng/dl)	406	6.9 (7.8)	5.6
Estimated Blood loss (ml)	341	406.2 (240.6)	350.0

Pathological stage

Pathological	Frequency	Cumulative %
Stage		
T1a	16	1.57
T1c	64	16.71
T2a	77	20.10
T2b	122	31.85
T2c	47	12.27
T3a	16	4.18
T3b	48	12.53
T3c	2	0.52

Advantages of LRP

Claims by LRP Surgeons	Rebuttal by open Surgeons
Magnification improves visualization	Magnification achievable with surgical loops
Less blood loss	Not clinically relevant, based on similar transfusion rates
Improved visualization allows for more precise dissection of the prostatic apex and NVB	Quality of life outcomes fail to show advantages for continence or potency

Advantages of LRP

Claims by LRP Surgeons	Rebuttal by open Surgeons
Avoidance of lower abdominal incision decreases postoperative pain and facilitates return to activities	Postoperative pain is comparable, and men can return to activities just as quickly despite an incision
Watertight urethrovesical anastomosis allows for earlier catheter removal	No difference in achieving watertight Vesicourethral anastomosis at postoperative day 3; urinary catheters typically removed at 1 week after both approaches

Robotic Prostatectomy

- A step sidewise at best, rather than a step forward, this is not ESWL
- We are 15 years behind breast cancer, colorectal cancer, and radiation oncologist who treat prostate cancer
- The Robotic prostatectomy is an example why

Point-Counterpoint: Prostate Cancer Robotic Surgery is Mainstream

Paul D. Maroni, MD Assistant Professor Department of Surgery/Urology



University of Colorado at Denver



Merriam-Webster Definition

Mainstream

Pronunciation: \man-strem\

Function: *noun* Date: 1599

: a prevailing current or direction of activity or

influence

— mainstream adjective

Wikipedia definition - Mainstream

- the common current of $\underline{\text{thought}}$ of the $\underline{\text{majority}}$.
- something that has ties to <u>corporate</u> or <u>commercial</u> entities.
- includes all <u>popular culture</u>, typically disseminated by <u>mass media</u>.
- The opposite of the mainstream are <u>subcultures</u>, <u>countercultures</u>, <u>cult followings</u>, <u>underground</u> <u>cultures</u> and (in <u>fiction</u>) <u>genre</u>.
- It is often used as a pejorative term.



Mistakes were made

- 2003 FTC allows purchase of Computer Motion, Inc by Intuitive Surgical, Inc for ~\$65M
- Price of daVinci surgical robot 2009
 - \$1.75M
- Estimated price with competition
 - Less than \$500,000
 - Source: Richard Satava MD FACS, lecture at Univ of Colorado General Surgery Grand Rounds, 2009

More mistakes

- Systematic problems force hospitals to compete
- Underserved areas think this will be an attraction
- Cancer reimbursed more favorably than other diseases
- Procedures reimbursed more favorably than most other options
- Isn't there enough other urologic disease?

Has the robot been oversold?

- Google.com search "robotic prostatectomy"
 - 127,000 hits
 - 11 paid sites on first page
- Intuitive Surgical, Inc.
 - Provides marketing advice/toolkits
- Strong incentives for medical centers' ROI
- Lost focus on patients during "dynamic growth curve" aka Gold Rush

Were there false expectations?

- Schroeck et al Eur Urol 2008
 - 400 patients surveyed from RRP and RARP 2000-2007
 - Equivalent functional outcomes and bother (EPIC) between RRP and RARP
 - More regret in RARP (24.1% v. 14.9%)

Patients who underwent RALP were more likely to be regretful and dissatisfied possibly because of high expectations of a new procedure. We suggest that urologists carefully portray the risks and benefits of new technologies during preoperative counseling to minimize regret and maximize satisfaction.

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Is one approach better?

available at more action addings, com journal homopage; www.europeanuralogy.com





Retropubic, Laparoscopic, and Robot-Assisted Radical Prostatectomy: A Systematic Review and Cumulative Analysis of Comparative Studies

Vincenzo Ficarra "-", Giacomo Novara", Walter Artibani", Andrea Cestari ^b, Antonio Galfano", Markus Graefen ", Giorgio Guazzora ", Bertrand Guilonneau ", Mani Menon", Francesco Montorsi ^c, Vipul Patel ^a, Jens Rassweller ^b, Hendrik Van Poppel ^l

■ Published 2009 - 103 references

Is one approach better?

- LRP/RARP less blood loss and transfusions
- Few or poor quality comparative studies
 - "...the data from this systematic review did not allow us to prove the superiority of any surgical approach...we do believe that it will never be shown that an LRP performed by a qualitatively poor surgeon would be better than an RRP done by a skilled surgeon (and vice versa)."

Is one approach better? Salvage treatment

- Hu et al J Clin Oncol 2008 need for salvage treatments - Medicare database
 - MIRP 27.8% v. Open RP 9.1%
- Chino et al BJU Intl 2009 904 RP (536 open)
 - No difference in indication or referral for RT
- Hu et al JAMA 2009 (adapted)

Can Tx/100y	MIRP	RRP	P
Overall	8.2	6.9	.35
Radiation	5.1	4.9	.67
Hormone	5.3	3.7	.21

Is one approach better? **Continence and Potency**

Incontinence*	MIRP	RRP	P
Diagnosis	15.9	12.2	.02
Procedures	7.8	8.9	.24
Erec Dysfunc*			
Diagnosis	26.8	19.2	.009
Procedures	2.3	2.2	.78

■ Medicare dbase study – MIRP >SES

2.18

■ No questionnaires used, early in learning curve

* - per 100 person years, adapted from	Hu et al JAN	AA 2009	
DEDCRECTIVES IN LIBOURS	DOIN!T		

Is robotic assistance or laparoscopy necessary?

- Most metrics appear equal
- Device is costly
- Costs are important
- Why use it?

The learning curve Proficiency # of times

The learning curve

The Learning Curve for Coil Embolization of Unruptured Intracranial Aneurysms

Vinorta Singh, Daryl R. Grow, Ramidd T. Higoshida, Christopher F. Dowd, Van V. Halback, and S. Claibone: Johnston

AUNI Am J Neurorediol 23:768-771, May 2002

■ First 5 cases -53% complications, after that 10%

Analysis of the Learning Curve in Telerobotic, Beating Heart Coronary Artery Bypass Grafting: A 90 Patient Experience

Richard J. Nevick, MD, Stephanie A. Fox, RBCP, Bob B. Kiali, MD, Larey W. Stitt, MS, Beitz Rayman, MD, Kojiro Kodena, MD, Allan H. Menkis, MD, and W. Dosoilas Bord, MD

■ Ann Thorac Surg 2003 – 9 of first 18 with major complications, 9 of next 72 with major complications

Learning curve important for open radical prostatectomy

- All outcomes improve with surgeon experience
- Critical number 200-500 cases
 - Catalona et al J Urol 1999 (single surgeon)
 - Klein et al J Urol 2008 (multiple surgeons, 4 centers)
- Argument for regionalization
- Fellowship training may reduce the learning curve
 - Rosser et al Cancer 2006
 - First 66 patients post fellowship, same outcomes

Learning curve robotic assisted radical prostatectomy

■ Are patients hurt by the learning curve?

Learning curve robotic assisted radical prostatectomy

- White et al Urol 2009
 - First 50 RARP compared to 50 historical RRP by same community surgeon (2005-2008)
 - Surgeon had performed >1200 RRP in career

	Margin positive	T2 (margin positive)
RRP	36%	34%
RARP	22%	19%

Adapted from White et al Urology 2009

Learning curve robotic assisted radical prostatectomy

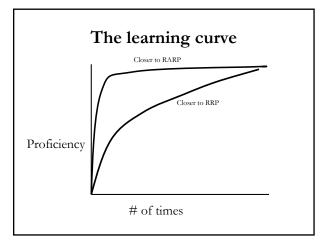
- Atug et al Eur Urol 2006
- First 100 RARP divided into thirds
- 3 advanced laparoscopic surgeons

#	1-33	34-66	67-100
+ margin	45.4%	21.2%	11.7%
T2 + margin	38.4%	13.7%	3.6%

Adapted from Atug et al Eur Urol 2006

Learning curve robotic assisted radical prostatectomy

- Patel et al J Urol 2005 (positive margins PSM)
 - First 100 13%
 - Second 100 8%
 - T2 5.7%
- Ahlering et al Urology 2004 (PSM)
 - First 45 35%
 - Next 60 16.7%
 - Next 60 T2 4.5%



Cost issues

- Technological costs decrease with time
- Must calculate in context of other treatments for PCa
 - RT highest cost (Crawford et al, presented at SCS AUA, 2009)
- Incremental cost will decrease as other specialties use more frequently

Why robot assisted radical prostatectomy?

- Patients deserve the procedure with the steepest learning curve (and hopefully proficiency is achieved in training).
- It allows what only a few could do well to be done by a wider array of surgeons.



Histologic Subtypes of Renal Cell Carcinoma

~ M. Scott Lucia, MD

Histologic Subtypes of Renal Cell Carcinoma



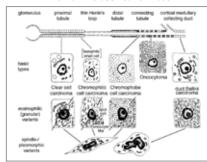
M. Scott Lucia, MD Chief of Genitourinary and Renal Pathology Director, Prostate Diagnostic Laboratory Dept. of Pathology University of Colorado Denver SOM

History of Classification of Renal Cell Neoplasms

- First case in literature reported by G. Miriel in 1810
- · First classification in 1826, proposed by König, on basis of *gross* morphologic appearance into four types: Fungoid, Medullary, Scirrhous, Steatomatous
- · Many subsequent classifications many based upon descriptive histologic features of tumors (archetectural and
- Mainz classification proposed by Thoenes 1986
 - based upon cytologic features of tumors
 - first to correlate the subtypes of tumors with cell of origin in

Delahunt B. Eble JN. History of the development of the classification of renal cell neoplasia. Clinics in Laboratory Medicine. 2005;25:231-46.

The Mainz Classification 1986



From: Delahunt B. Eble JN. Clinics in Laboratory Medicine. 2005;25:231-46. © 2005 Elsevier Inc.

Studies have confirmed cytogenetic differences between major tumor subtypes in Mainz classification

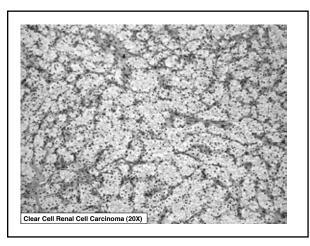
Tumor type	Freq	Histopathology	Cytogenetics
Clear cell RCC	70%	-Clear cytoplasm -Alveolar, tubular and cystic architecture -Vascular stroma	-3p, +5q, -6q, -8p, -14q
Chromophil RCC	15%	-Papillary architecture -basophilic, low N:C (type I) -eosinophilic, high N:C (type II)	Trisomy 7, 17, -Y, +3q
Chromophobe RCC	5%	-Solid architecture -Pale or granular cytoplasm -Prominent cell membranes -Occ. Bizarre nuclei	-1, -2, -6, -10, -13, -17, -21
Collecting duct Carcinoma	1-2%	-Medullary location -Tubuloglandular architecture -Hobnail cells -Desmoplastic stroma	-1q, -6p, -8p, - 13q, -21q

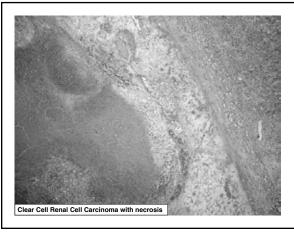
Heidelberg Classification 1997¹

Expanded on Mainz classification; based upon cytogenetics

- · Clear cell "conventional RCC"
- Papillary RCC to replace "Chromophil"
- · Chromophobe RCC
- · Collecting duct carcinoma
 - Medullary carcinoma associated with sickle cell trait

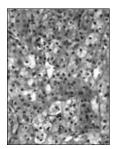
1. Kovacs et al. J Pathol 1997;183:131-3.



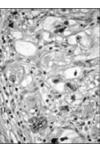


Fuhrman grading predictive of outcome

Fuhrman grade







Clear Cell RCC - Cytogenetics

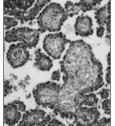
- Abnormalities involving VHL gene (3p25.3) (tumorsuppressor gene):
 - Deletion (3p-)
 - Translocation (3;6, 3;8, 3;11)
 - Somatic mutation or hypermethylation (80% RCC)
 - In both sporadic (95%) and familial (4%) RCC
- Familial, associated with VHL (Von Hippel-Lindau) syndrome:
 - Hemangioblastomas of the cerebellum and retina
 - Bilateral renal cysts
 - Multiple RCCs (nearly all, if they survive older age)

VHL Gene

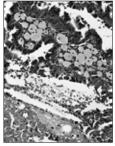
- VHL protein part of ubiquitin ligase complex
 - Degrades hypoxia-inducible factor (HIF-1)
 - Degrades insulin-like growth factor-1 (IGF-1)
- · Loss/ mutation results in:
 - High levels of HIF-1 (stimulates angiogenesis via VEGF and TGF-b)
 - Upregulation of IGF-1 (stimulates cells growth)

Papillary RCC

Basophilic (Type I)



Eosinophilic (Type II)

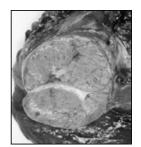


Papillary RCC

- · Hereditary and sporadic forms
 - Hereditary usually multifocal and bilateral
- Most common cytogenetic abnormalities:
 - Trisomy 7, 17 (hereditary and sporadic forms)
 - Loss of Y in male patients (sporadic form)
- Protooncogene locus on chromosome 7 (cMET):
 - Tyrosine kinase receptor for HGF
 - Mutated in some sporadic cases

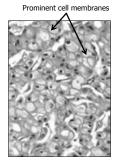
Chromophobe renal cell carcinoma

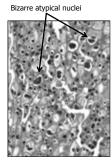
- 5% of RCC
- Gross appearance:
- Solid tumor
- Mimics oncocytoma
- Derived from intercalated cell of collecting duct
- Numerous mitochondria and mitochronria-derived cytoplasmic vesicles



Chromophobe renal cell carcinoma

Fuhrman grading not reliable

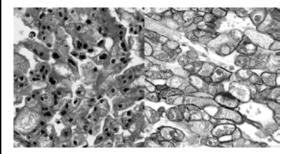


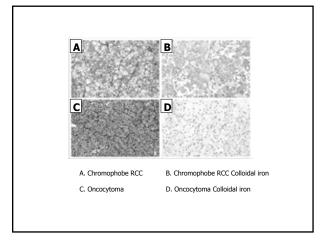


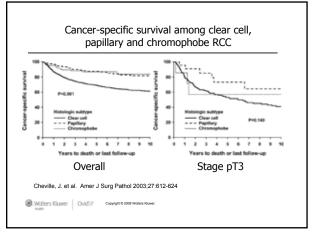
Chromophobe RCC

Eosinophilic variant

CD117 Expression

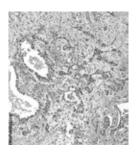






Carcinoma of the Collecting Ducts of Bellini (Collecting Duct Carcinoma)

- · Centrally located
 - Medullary origin
- · Derived from principal cell of collecting duct
- Usually present in advanced stage and higher grade
- Medullary carcinoma
- Aggressive variant of CDC that occurs in young black males with sickle cell trait



2004 World Health Organization **Classification of Renal Cell Tumors**

Expanded on Mainz and Heidelberg classifications to account for cytogenetics, behavior, and associated conditions

- Clear cell RCC
- Multi-locular clear cell RCC (VHL gene mutation, good prognosis)
- Papillary RCC (Type l=basophilic, good prognosis; type II=eosinophilic, worse prognosis)
 Chromophobe RCC
- Carcinoma of the collecting ducts of Bellini Renal medullary carcinoma
- · Xp11 translocation carcinoma
- Carcinoma associated with neuroblastoma Mucinous, tubular, and spindle cell carcinoma
- Renal cell carcinoma, unclassified
- · Papillary adenoma

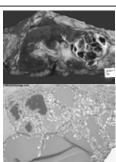
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 Carcinoma of the collecting ducts of Bellini
- Renal medullary carcinoma
- Xp11 translocation carcinoma
- · Carcinoma associated with neuroblastoma
- Mucinous, tubular, and spindle cell carcinoma
- · Renal cell carcinoma, unclassified
- · Papillary adenoma
- Oncocytoma

Multilocular cystic renal cell carcinoma

- · Good prognosis
- Most low grade (Fuhrman I or II)
- · Usually stage I or II
- · Mets not reported
- VHL mutations



2004 World Health Organization **Classification of Renal Cell Tumors**

Expanded on Mainz and Heidelberg classifications to account for cytogenetics, behavior, and associated conditions

- Multi-locular clear cell RCC (VHL gene mutation, good prognosis)
- Papillary RCC (Type I=basophilic, good prognosis; type II=eosinophilic, worse prognosis)
- Chromophobe RCC
 Carcinoma of the collecting ducts of Bellini
- Renal medullary carcinoma
- Carcinoma associated with neuroblastoma
- Mucinous, tubular, and spindle cell carcinor · Renal cell carcinoma, unclassified (5% of RCC)
- · Papillary adenoma
- Oncocytoma

Conclusions

- · The classification of renal cell carcinomas is expanding
- · Classification has morphological and cytogenetic basis
- · Proper classification important for prognosis

Point-Counterpoint: Small Renal Masses

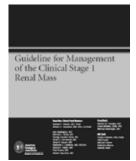
Best to Remove ~ Paul D. Maroni, MD Best to Watch ~ Donald L. Lamm, MD

Point-Counterpoint: Small Renal Masses Best to Remove

Paul D. Maroni, MD Assistant Professor Department of Surgery/Urology



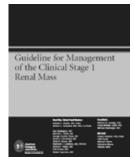
AUA Clinical Guidelines 2009



Index 1 patient: SRM and healthy

- Standard Partial nephrectomy if able
- If PN not feasible, then radical nx
- Cryo, RFA, and surveillence are options

AUA Clinical Guidelines 2009



Index 1 patient: SRM and not healthy

- Standard Partial nx or radical nx
- Cryo, RFA, and surveillence are recommendations

Small renal mass Best to remove

■ Definition – enhancing renal mass ≤4cm (clinical T1a)

SRMs - Best to remove

Why?

- Minimal risk
- Effective treatment
- A real medical threat
- Improvements in peri-operative care

Risk of partial nephrectomy



Laparoscopic versus Open Partial Nephrectomy: Analysis of the Current Literature

Francesco Porpiglia", Alexanniro Volpe, Michele Billia, Roberto Mario Sozrpu

	# Pts	Size	Compl.	Medical	Leak
Open	2756	3.2	21.3%	10%	3.9%
Lap	1062	2.7	21.4%	9.6%	4.2%

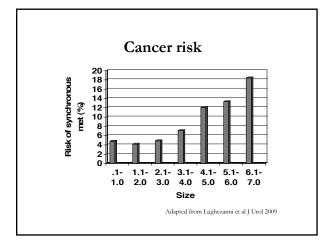
Adapted from Porpiglia et al Eur Urol 2008

Contemporary reality

- 1-3 day hospital stay (even with open surgery)
- 3-4 weeks of convalescence
- 98% 10-yr cancer specific survival
 - 100% with smaller tumors?
- ~4% local recurrence

Exceptionally low-risk in healthy patients with excellent cancer control

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Cancer Risk

- Cripen et al Cancer 2009
- 173 patients with enhancing renal mass on AS
- 24 month median f/u
- 1.3% developed metastasis
- 15% exhibiting growth still had benign tumors

Development of metastasis in 2-yrs as high as 10-yr CSS for PN. Growth a poor indicator of cancer.

Cancer Risk

Growth Kinetics of Renal Tumors/Crispen et al

low risk of disease progression, the excellent oncologic outcomes obtained with prompt surgical intervention continue to indicate that extirpative therapy in acceptable candidates should remain standard. Identification of clini-

cal, radiographic, pathologic, and molecular correlates of a tumor's biologic potential is essential to avoid potential overtreatment of otherwise indolent asymptomatic

Real-life case

- 1987 63 yo male with abnormality on IVP in upper pole of right kidney
- 2004 81 yo male has 3-4cm mass identified in upper pole of right kidney. Cardiologist told him his cardiac risk was too high. Urologist told him his heart would kill him first.
- 2005 4cm continue to watch
- 2006 5cm continue to watch

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Real-life case

 2007 – 7cm, losing weight. Thinking more seriously about surgery. Saw cardiologist, PCP – all said not to operate.

UROLOGY 64: 909-913, 2004.

MANAGEMENT OF RENAL MASSES IN PATIENTS MEDICALLY UNSUITABLE FOR NEPHRECTOMY—NATURAL HISTORY, COMPLICATIONS, AND OUTCOME

GAYEN W. A. LAMIS, EMBA J. ERONWICH, PAUL VASEY, 2019 MICHAEL AFFICIESON

- 36 patients with renal masses 3.5-20cm in size (median 6)
- 23 had biopsy confirming RCC
- No deaths from cancer progression
- Generally slow growth (0.4cm/year)

Real-life case

- 2007 7cm, losing weight. Thinking more seriously about surgery. Saw cardiologist, PCP – all said not to operate.
- 2008 10 cm, flank pain. Local spread to liver and lung.
- August 2008 dead from kidney cancer.

Acceptable candidates?

- How old is too old?
- How ill is too ill?

Example: elective abdominal aortic aneurysm repair in people over 80 years old

■ Mortality 5.6% at one year

Example: Hypertrophic cardiomyopathy

■ In hospital death – 6.7%

Ballotta et al Minerva Med 2009; Hreybe et al Clin Cardio 2006

Advice to patients (and practitioners)

- Do not discount surgery with the "eye-ball" test.
- Consultation with cardiologist and anesthesiologist.
- Balance surgical risks and cancer risks.
- Growth not indicative of cancer, but probably of malignant potential.

Small Renal Masses: The Case for Active Surveillance

Don Lamm, M.D.

Clinical Professor of Urology, University of Arizona, and Director, BCG Oncology, Phoenix, AZ

BCGOncology.com

The Old is New Again!

- Stage A1 prostate cancer (well differentiated, focal disease on TURP) does not require treatment. Now: "Active Surveillance"
- Renal adenoma less than 3 cm are "benign." Now: small renal masses (SRM) do not necessarily require treatment, i.e: Active Surveillance.

Small Renal Masses (SRM)

- Imaging: >2/3 renal tumors found incidentally
- 85% ↑ renal ca (RCA) 1994-2002; 330% ↑ in 2-4cm tumors.
- Mortality not increasing despite ↑ incidence
- Renal adenoma, indistinguishable from renal carcinoma, found in 7- 22% at autopsy*
- Increased incidence SRM with age, most >65
- >30% of those >70 die of unrelated causes <5 years post RCA surgery

Jewitt, Urol. Clin N Amer. 2008; * Bonsib, GU Onc. 1985

Natural History of SRM

- 20% of solid small renal masses are BENIGN!
- Carcinomas less than 3cm have a remarkably benign course: <1% progressed (2/200+, one with 1.3cm/yr ↑)
- · Mean growth in 234 SRM: 0.28cm /year
- Lack of growth does not prove SRM is benign, but rapid growth risks progression
- Growth inversely proportional to age, supporting intervention in younger patients
- · First do no harm! What about biopsy?

Jewitt, Urol. Clin N Amer. 2008; Crispen, BJU Int. 2007

Jewitt, 610	i. Cili IV Allici. 2006,	Crispen,	DJC III	. 4
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Needle Biopsy of SRM

- Old Concept: Risk of bleeding, risk of seeding; necrosis, false negative biopsy common.
- New Concept (the facts):
 - Small cores or FNA rarely produce bleeding or AV fistula
 - Only 6 reported cases of tumor seeding (<0.01%);
 none recently with canula technique, small needles
 - FNA and core biopsies are accurate with experience: (97% sensitivity, 100% specificity)

Rodriguez, Sem Urol Oncol. 1995; Jewitt, Urol. Clin N Amer. 2008

Does Delay Affect Outcome? Rais-Bahrami: BJU Int. 103:1355-8, 2009

- 32 with SRM, mean 2cm; 5 yr follow
- 3 or more month delay (mean 16 months) in LPN compared with standard
- Mean growth .56cm/yr
- No increase in operative complications, blood loss or time.
- · No local or distant recurrence

How Effective is Cryoablation of SRM? Stein: J Endourol. 22:2433-9, 2008.

- 30 SRM underwent lap cryoablation
- 84% had no enhancing mass at 3 months
- 90% by 6 months, only 1 (3%) of these 3 persisted by 9 months
- Lap partial nephrectomy on this mass showed no remaining carcinoma
- 100% short term (one year) complete response.
- Residual enhancement by 9 months may not indicate failure

Meta-analysis: Cryo vs RFA Kunkle: Cancer. 113:2671-80, 2008

- 47 series, 1375 SRM's
- Local progression: Cryo 5%, RFA 13% (p<.0001)
- Repeat ablation: 1% Cryo, 8% RFA (p<.0001)
- Metastasis: 1% Cryo, 2.5% RFA (p=0.06)
- Response criteria and short term follow up favor cryoablation over radio frequency ablation, though RFA is more frequently done percutaneously

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A Brief History of Renal Cancer, SRM, Surgery

- 1963: Robson demonstrates improved survival with radical nephrectomy.
- 1992: Aso reports 8% improved survival in incidental vs symptomatic masses demonstrated by ultrasound (but not IVP). Since RCC is only 2-3% of malignancy, routine US screening is not recommended, but many include renal evaluation in any abdominal US.
- any abdominal US.

 1990's: Partial nephrectomy established as treatment of choice for SRM: 90-100% DSS, 0-7% local recurrence in 909 pts/17 series, 1986-2002. Survival equal in tumors 4 or less cm (T1a), significant reduction in renal insufficiency. Progress in PNs now appropriate for selected cases >4cm, with several studies showing equality to radical nephrectomy for T1b (4-7cm) tumors.
- 2000's: Lap partial nephrectomy (LPN) shown to provide equal efficacy and renal function compared with open (OPN) for tumors 7cm or less. 1800 pts, 3 yr DSS 99.3% LPN, 99.2% OPN; renal function: 97.9 vs 99.6% in nonrandomized (therefore selected) series (Gill. J Urol. 178: 41-6, 2007). Operating time and blood loss less with LPN. Shorter hospital stay> decreased cost for LPN (without robot).
- 2006: Cryoablation for SRM: 5 year follow up shows 98% DSS in 66 pts (Hegarty). Percutaneous approach for posterior tumors shows minimal morbidity. Percutaneous RFA is less established, possibly less effective, but can provide good (83-100% at 20 month) DSS in SRM.
 2005: Weld and Landman: Meta-analysis of RFA vs Cryo vs LPN: Local recurrence 7-,9 vs 4.6 vs 2.7%; RFA not yet proven to be reliable; Recurrence less in <3.5cm tumors. (BJU int. 96:1224-9).

Conclusions

- · Increased imaging in our aging population may create an epidemic of SRM (up to 22% at autopsy)
- 1/5 SRM are totally benign, and biopsy is now safe and accurate.
- Small adenocarcinomas are low grade & not aggressive
- · Incidence increases with age, as does co-morbid conditions and risk of dying from other causes
- With only 1% progression for SRM, those with a life expectancy of 5 or less years may benefit from active surveillance, which should clearly be offered

Female Urology "Potpourri"

~ Brian J. Flynn, MD

Female Urology/Urogynecology Potpourri

Brian J. Flynn, MD Director of Urogynecolgy, Reconstructive Urology and Urodynamics

Associate Professor of Urology/Surgery University of Colorado Denver Denver, CO



Perspectives in Urology 2009

Urinary Tract Infections (UTIs) in Women

Perspectives in Urology 2009

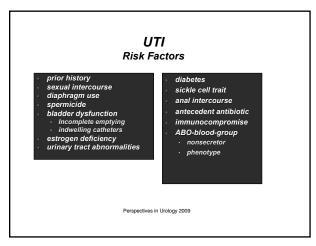
UTI Introduction

8 million visits to health care providers annually *
lead to more than 1 million admissions
more than \$1.6 billion annually in health care dollars
wide spectrum of disease from mild cystitis to lifethreatening urosepsis

* Gupta K, et al: Ann Intern Med 2001

LUTI Epidemiology • female predominance: 30:1° • 50% of females will have a UTI • 50% will have a recurrent infection • most common infectious complication in pregnant women • bacteriuria more likely to develop into pyelonephritis (28% v. 1.4%) • UTIs more common in male neonates and infants • males > 50 have incidence similar to age matched females • Foxman B: Am J Med 2002

UTI Pathogens Hospital acquired Community acquired Staph. saprophyticus S. Saprophyticus Proteus mirabilis Klebsiella Klebsiella Citorbacter Enterococcus faecalis Serratia P. aeruginosa S. epidermidis Candidia Perspectives in Urology 2009



UTI Treatment Considerations - goal - Eradication /sterilization of the urinary tract - treatment must consider - extent of patient's illness - past history of disease - patient's urologic status - other disease states - local susceptibility patterns - most experts prefer bacteriocidal agents

UTI Asymptomatic Bacteriuria

- generally does not require screening or treatment except in pregnancy
- risk of subsequent pyelonephritis in pregnancy increases to 28% treatment does not decrease incidence of positive follow-up cultures and may increase resistance no treatment is indicated until the patient becomes symptomatic

Perspectives in Urology 2009

UTI Acute Uncomplicated Cystitis

Short Course

Extended Course

- acute symptoms lack of systemic symptoms duration < 48 hours
- infrequent recurrence availability for reliable f/u
- male, older systemic toxicity concomitant diseases
- recurrence nosocomial
- tract abnormalities lack of follow-up

Perspectives in Urology 2009

UTI Acute Uncomplicated Cystitis

- duration of treatment
 Single dose v. Jay v. longer
 Single dose v. Jay v. longer
 Single dose v. Jay v. lost favor as recent evidence suggests lower
 cure rates and higher recurrence
 3 day regimen is generally preferred in relatively healthy adults
 can treat empirically without culture results in appropriate candidates

* Clin Infect Disease 1999;29:745

Perspectives in Urology 2009

UTI Acute Uncomplicated Cystitis

- Single-dose treatment
 TMP/SMX DS x 2 tablets
 Ciprofloxacin 500 mg x 1
 Fosfomycin x 1 dose
 Three day treatment
 TMP/SMX DS BID

- Ciprofloxacin 250 mg BID*
 Other Beta-lactams
 Longer course may be used

* Clin Infect Disease 1999:29:745

UTI Complicated Cystitis

patients predisposed to recurrent infection or treatment failure anatomic or functional factors

anatonic or indicatoria factor.
DM, pregnancy
h/o pyelonephritis
men > 50 years of age
urine culture necessary
oral fluoroquinolone 1st line
10-14 day course

* Clin Infect Disease 1999;29:745

Perspectives in Urology 2009

UTI

Recurrent: Same or organism or different*

symptomatic UTI that follows clinical resolution of an earlier UTI

common in post-menopausal women

residual urine

changes in microflora

college women

27% experience at lest 1 Cx proven recurrent UTI within 6 months of tx

* Orenstein R, et al: Am Fam Physician 1999

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UTI

Prophylactic/Suppressive/Self-Start ABX Therapy

If a women experiences > 3 UCx proven UTIs/year

Options

postcoilal abx therapy if occurs following sex

self-start (3-day) therapy if no causal relation

suppressive abx therapy if more severe infections

Suppressive abx therapy x 3 -6 months, stop then re-asses

Nitrofurantoin 50 mg daily

Bactrim DS ½ tablet daily

TMP 100 mg daily

Norfloxacin 200 mg daily

Perspectives in Urology 2009

Vulvovaginal Candidiasis 'Vaginal Yeast Infection'

- ncomplicated VVC Treatments
 short courses of treatment (1-3 days) adequate for most uncomplicated cases; improved compliance
 Clotrimazole 1% cream 1 applicator intravaginally for 7-14 days
 Clotrimazole 500 mg vaginal tablet x 1 dose
 Terconazole 6.5% ointment one applicator x 1 dose
 Terconazole 0.4% cream one applicator QD x 3 days
 Terconazole 80 mg vaginal suppository x 3 days
 Fluconazole 150 mg tablet PO x 1 dose

Catheter Associated UTI (CAUTI)

Saint, S. et. al. Ann Intern Med 2009;150:877-884

Inditional Psyment*

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Hospital-Acquired Conditions Not Eligible for Additional Payment

Catheter Associated UTI (CAUTI)

- UTI is the most common hospital acquired infection
- 1 in 5 patients in the hospital receive a Foley catheter
- 1 day of catheter use = 5% increase in bacteriuria
- CAUTI costs at least \$600 and each episode of urinary tract-related bacteremia costs at least \$2800
- Short-term catheterization was defined as up to and including 14 days

Perspectives in Urology 2009

CAUTI Microbiology

- 40% E coli
- 30% Pseudomonas aeruginosa,
- 30% -gram positives, staph/strep and Candida
- the investigators did not include fungal urinary tract infections as part of their study

Wagenlehner FM et al.: Int J Antimicrob Agents 2008

Perspectives in Urology 2009

CAUTI

Recommendations for Hospitals to Address the Centers for Medicare Medicaid Services Rule Changes Regarding Catheter-Associated Urinary Tract Infection

Use only when medically indicated · retention or high risk of retention

- monitoring of urinary output
- incontinence associated with risk of skin breakdown

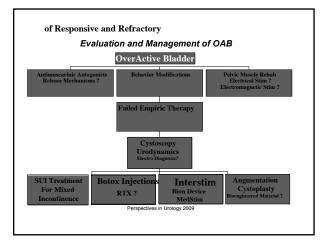
specific surgical procedures (RRP, cryo, reconstruction)

Proper insertion techniques

- training standards for insertion and managing catheters
- hand hygiene, aseptic catheter insertion, and proper maintenance by using a closed urinary drainage system
- daily review of necessity "reminders and stop orders"
- > Develop systems for removal of catheters without physician order

Saint, S. et. al. Ann Intern Med 2009

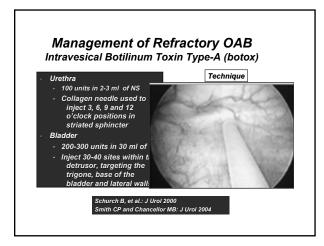
OAB Perspectives in Urology 2009

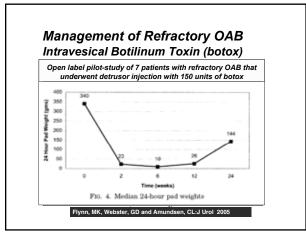


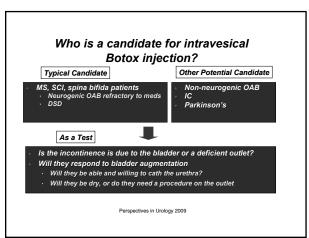
BOTOX Perspectives in Urology 2009

Some Published Uses of Botulinum Toxin Type A Occupational Dystonia Achalasia Blepharospasm Pain (muscle spasm) Cervical Dystonia Spasmodic Dystonia Essential Tremor Strabismus Headache & Migraine Hemifacial Spasm Hyperhydrosis Stroke Myofascial Pain Traumatic Brain Injury Cosmetic use is the most common application Perspectives in Urology 2009

Management of Refractory OAB Intravesical Botilinum Toxin (botox) Botox is derived from the organism C. botulinum Inhibits the vesicular neuronal blockade up to 9 mos Increasing data on the benefits of botox in patients with Non-neurogenic DO Neurogenic DO DSD Interstitial cystitis? Schurch B, et al.: J Urol 2000 Smith CP and Chancellor MB: J Urol 2004







How close are we to approval of Botox for idiopathic OAB?



- MS SCI Spina bifida

- NOAB studies completed enrollment 3-09

 An additional 12-18 months will be required before FDA approval may be anticipated, once studies completed

Perspectives in Urology 2009

Neuromodulation

Perspectives in Urology 2009

Management of Refractory OAB Sacral Neuromodulation

Introduced after the pioneering work of Tanagho and Schmidt for voiding dysfunction
Neuromodulation of the micturition reflex manages urinary symptoms through the stimulation of the afferent pelvic nerves

Therapy



Beneficial in patients with refractory OAB demonstrating a reduction in frequency, urgency, urge incontinence

Treatment modality is based on unilateral or in some cases bilateral stimulation of the sacral nerves, most commonly S3

Tanagho EA, Schmidt RA and Orvis BR: J Urol 1989 Schmidt RA, et al.: A.: J Urol 1999 Hassouna MM, et al.: J Urology 2000

How much stimulation is necessary? Unilateral vs. Bilateral

- For urge-incontinence stimulation of the S3 nerve root unilaterally is often sufficient
- For direct motor stimulation to produce micturition, bilateral stimulation of the motor roots is necessary
- For management of chronic pelvic pain, bilateral stimulation of the S3-4-5 dorsal roots is often necessary

Who do I Implant Characteristics Women respond better than men Women respond better una men Younger patients (< 65) respond better than elderly Non-neurogenic do better then neurogenics Urge, frequency and urge incont. responds better then retention Ideal Candidate Young female with urge, frequency, urge incontinence (without IC/CPP or neurologic condition) refractory to anti-muscarinics Perspectives in Urology 2009

Management of Pelvic Organ **Prolapse**

Perspectives in Urology 2009

Anatomy of Vaginal Support POP Location 1 Anterior and apex 20% Posterior only Posterior and apex Anterior compartment involved Highest failure in anterior 30-70% 2-6 compartment een et al. Obstet Gymcol 1997;89:501-506 ull et al. Am J Obstet Gymcol 1992;166:1764-1768 lley et al. South Med J 1995;385:47-596 untelsson et al. Am J Obstet Gymcol 1999;180:299-305 ull et al. Am J Obstet Gymcol 2009;183:1863-1873 beet et al. Int Urgymcol J Pelvis Pt Dysfum 2001;12:178-186

How are we doing with our current surgical procedures?

- 11.1% lifetime risk of surgery
- 29-40% patients require reoperation within 3 years^{1,2}
- 60% of the recurrences are at the same site³
- 32.5% of the recurrences are at a different site³
- ¹ Olson et al. Obstet and Gynecol 1997;89:501-506 ² Marchionni et al. J Reproduct Med 1999;44;679-684 ³ Clark et al. Am J Obstet and Gynecol 2003;189:1261-1267

Pelvic Floor Reconstructive Surgery **Use of Synthetics**

<u>Advantages</u>

- Readily available Less expensive
- Surgical "kit"
- Predictable in vivo response
- No disease transmission
- Not biodegradable

Disadvantages

- Urinary tract erosions Vaginal wall extrusions
- Graft contraction

Perspectives in Urology 2009

Management of Vaginal Vault Prolapse

Dependent on patients age, overall health and degree of physical and sexual activity ${}^{\circ}{}^{\dagger}$

Patient that is physically and sexually active with minimal comorbid conditions



Abdominal sacral colpopexy

'Older' patient that is physically inactive with some comorbidities



Polypropylene mesh reinforced pelvic floor repair and vaginal vault suspension (Total Prolift)

- Flynn, BJ and Webster, GD: Curr Opin Urol 2002
- † Amundsen, CL, Flynn, BJ and Webster, GD: J Urol 2003 Perspectives in Urology 2009

Analysis of Polypropylene Mesh Properties

			ETHOON	ETHOON	ETHOON	A96	ARS	BARD	BOSPICK BOX
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Sending Stiffness	Lateral Frankliky	-	186	404	179	142	18.6	90	279
Sindy	conglisations	-							

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Reinforced Vaginal Repairs for POP "Prolapse Kits"

Consists of a transvaginal extraperitoneal SSLF accomplished by placement of polypropylene mesh in the vaginal apex, anterior (vesico-vaginal space) and/or posterior (recto-vaginal space) compartments

- Minimally invasive
 Trocar driven approach
 Vesicovaginal space
 Paravaginal space
- Pararectal space Obturator canal
- Minimal evidence
- Safety profile
- Intraoperative Postoperative



PROLIFT System: Early Outcome Data1

Author	# Pts.	Mean Age	Site	Complications	Exposure	Length of Follow Up	"Success" (≤ Stage II)
Cosson M et.al. (France)	90	65.3	A-1 T-89	Rectal perf-1 Hemmorrhage-2 VVF-1	9 (10%) S=5 (56%)	12 mo.	74 (81.6%)
Fatton BF et.al. (France)	110	63.2	A-22 P-29 T-59	Cystotomy-1 Hematoma-2 Vd. Dysfcn6	5 (4.7%) S=2 (40%)	3 mo.	105 (95.3%)
Murphey M et.al. (USA)	89	65	A-48 P-11 T-30	Cystotomy-2	0 (0%)	5 mo.	84 (94.4%)
Hinoul P et.al. (France)	29	62	A-29	Cystotomy-1	2 (6.9%) S=N/A	6 mo.	28 (96.5%)
Withagen MIJ et.al. (Netherlands)	43	66	A-11 P-16 T-5	Cystotomy-2 Rectal perf1 Vd Dysfcn-1	2 (4.7%) S=N/A	6 mo.	35 (81.4%)

1UGA – Fatton - 2006 Abstracts all published in: Int Urogynecol J 2006;

PROLIFT System: Early Outcome Data1,2

Author	# Pts	Mea n Age	Site	Complications	Exposure	Length of Follow Up	"Success" (≤ Stage II)
Groenen MJC et.al. (Netherlands) ¹	26	61	A-6 P-10 T-10	Vd.dysfcn-5	1 (3.8%) S=N/A	2 mo.	26 (100%)
Perscheler M et.al. (Austria) ¹	80	N/A	N/A	Cystotomy-2 Hematomas-2	8 (10%) S=5 (50%)	N/A	N/A
Rivera JM et.al . (USA) ²	82	63	P-19 T-63	Hematoma-1 Hemmorrhage-1	7 (11.7%) S=N/A	3 mo.	Not well defined
Compiled Data	549	64	A-109 P-85 T-256	Cystotomy- 1.7% Rectal perf- 0.4% Hemorrhagic- 1.3% Void dysfcn- 6.7%	34 (6.2%) S=12 (2.6%)	6 mo.	81.4-100%

¹ IUGA – Fatton - 2006 Abstracts all published in: Int Urogynecol J 2006;17(S.2):S212 ² AUGS 2006 Abstract published in: Int Urogyn J 2006;17(S.3):S460

NICE Review



Systematic review of the efficacy and safety of using mesh or grafts in surgery for anterior and/or posterior vaginal wall prolapse

Xueli Jia, Cathryn Glazener, Graham Mowatt, Graeme MacLennan, Cynthia Fraser, Jennifer Burr

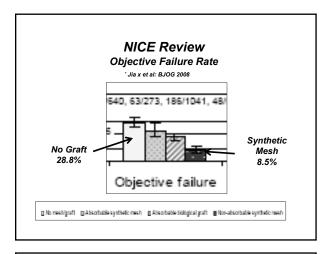
October 2007

Perspectives in Urology 2009 * Jia x et al: BJOG 2008

NICE Review

- National Institute for Health and Clinical Excellence (NICE)
- · Provides national clinical guidelines in the UK
- Examined surgical repair of vaginal prolapse using mesh
- Evaluated 446 reports 49 studies selected
- 4569 patients in total

* Jia x et al: BJOG 2008



Management of Pelvic Organ Prolapse

Mesh Complications

	Erosion rate	Dyspareunia
Amrute, 2007	2.1%	10%
Hiltunen 2007	17.3 (most asymptomatic)	
Fatton 2007	4.7	10
DeTayrac 2007	6.3	12.8
DeVita 2008	3.8	1.3
Nguyen 2008	5 (all txd in office)	Mesh 9% No mesh 16%

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Polypropylene mesh reinforced pelvic floor repair and vaginal vault suspension (Prolift)

* Flynn BJ, et al: SC AUA 2007

28 women with Stage III POP or greater treated with Prolift ± TVT in a 12 month period were evaluated

Prolapse Outcome

Prolapse was cured in 27 of 28 patients (Stage 0-I prolapse) · 1 rectocele following anterior implant only

Continence Outcome

SUI cured in 13 of 13 patients that underwent TVT · 5 of 12 that did not undergo TVT developed de novo SUI

· 2 of 3 urethrolysis patients remained dry

Perspectives in Urology 2009

Polypropylene mesh reinforced pelvic floor repair and vaginal vault suspension (Prolift)

* Flynn BJ, et al: SC AUA 2007

All patients were discharged within 24 hours of surgery All patients returned to normal activity, with the exception of heavy lifting, in < 7 days

Complications

Convalescence

No urinary tract erosions, bowel, ureteral, vascular or nerve injuries

1 patient with delayed bleeding required replacement of vaginal pack for additional 48 hours

2 vaginal mesh extrusions noted with in 3 months of surgery

Local excision of mesh and multi-layer closure performed
 No recurrent extrusion

Incidence of vaginal erosion following anterior prolapse repair with polypropylene mesh

Single vs. double layer vaginal wall closure

Terlecki RT and Flynn BJ et al: AUGS 2009

75 cases of mesh reinforced anterior repair (anterior Prolift™) for cystocele performed by a BJF (2005-2008) were analyzed

Closure	Mean age (y)	Prior Repair (%)	Prior Hystx (%)	Mean LOS (d)	Mean DOC (d)	Mean F/U (mos)
SL	65	42	64	1.0	1.8	25
DL	63	59	67	1.2	2.8	10

Comparison of mesh extrusion rate following a single layer vaginal wall closure (n = 39) v. double layer closure (n = 36)

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Full-Thickness Vaginal Incision

- Identify the true
 vesicovaginal and
 rectovaginal spaces
 Consensus of experience- full
 thickness leads to lower
 extrusion rates
- 3-5 cm length with effort to keep incisions small Avoid the apex transverse incision

Perspectives in Urology 2009

Incidence of vaginal erosion following anterior prolapse repair with polypropylene mesh Single vs. double layer vaginal wall closure Terlecki RT and Flynn BJ et al: AUGS 2009

Outcome			
Closure	POP Cure (%)	Erosion (#, %)	
SL	97	6/39 (15%)	
DI	97	0*	

All vaginal wall extrusions were on the anterior incision

- · 2 healed after office excision
- 4 required multiple OR excision, reclosure of vaginal incision

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What to do with the opposite compartment? **Concomitant Repairs**

Anterior/Posterior Compartment

Prolapsed

Significant apical prolapse, large enterocele

No prolapse in opposite compartment –No consensus

- Treat with standard repair Reinforced repair in lesser compartment
- Leave untreated if asymptomatic

Perineal body

Not advisable to treat asymptomatic perineal relaxation If symptomatic and there is laxity

repair separately "distal" to the mesh Perspectives in Urology 2009

What to do with the urethra? Concomitant TVT

SUI Surgery

- Sling if

 History of SUI

 UDS evidence of SUI with prolapse reduced

 Stage Ill or IV cystocele and no prior sling

 Stage patient if

 No history or UDS evidence of SUI

 Prior successful sling in patient with large cystocele

 No SUI in patient with posterior or apical prolapse only

 Bladder incomplete emptying/retention in patient ± prior sling

Perspectives in Urology 2009

Management of Complications of SUI and Prolapse Surgery

Perspectives in Urology 2009

Complications What could happen?



Intraoperative

Hemorrhage

Bowel injuries

Bladder and Urethral injuries

Ureteral Injuries

Postoperative

- Fistula
- Urinary retention

- Osteitis Pubis Infection Voiding dysfunction
- Failures

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Vaginal Wall Extrusion and Urinary Tract Erosion Incidence

Vaginal wall mesh extrusion occurs in 0.5 - 3% of patients and is usually amenable to tranvaginal partial mesh excision † ‡

Urinary tract erosion is a more severe complication (< 1%) and may be treated with endoscopic or open partial excision

* Bemelmans BLH and Chapple, CR: Cur Opin Urol Urol 2003 † Meschia M, et al: IntUrogynecol J Pelvic Floor Dysfunct 2001 ‡ Giri SK, et al: Urol 2007



Graft Complication

CU Criteria for Simple v. Complex Graft Complications

	Simple	Complex
Mesh Type	Type 1 mesh	Type 2, 3, 4 mesh especially if mesh has been withdrawn from market
Timing to presentation	early < 6 weeks	delayed ≥ 6 weeks
Location of extrusion	suture line	remote from suture line
Depth of mesh	deep	embedded in vaginal wall, "cobblestone vagina"
Prior excisions	none	≥1
Associated inflammation	none/minim al	obvious purulence
Affected organ	vagina only	bladder, urethra, rectum

Terlecki RT and Flynn BJ: AUA update series 2010

Vaginal Wall Mesh Erosion

Predisposing Factors

Etiology

Ischemia, infection, iatrogenic

Patient characteristics

Vaginal infection

- Elderly Post-menopausal Radiation

Surgical factors

- **Button holes**
- Unrecognized trocar injury
- Hematoma, infection, would closure

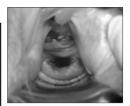
Terlecki RT and Flynn BJ: AUA update series 2010

Vaginal Wall Mesh Extrusion Diagnosis

Diagnosis

High index of suspicion vaginal bleeding > 6 wks dyspareunia 'scratchy vaginal wall' partner pain on intercourse ('hispareunia')

Meticulous follow-up 6 wks, 3 mos, 1 yr and PRN ear plastic speculum



Terlecki RT and Flynn BJ: AUA update series 2010

Vaginal Wall Mesh Extrusion Prevention During Prolapse Surgery

Intra-operative

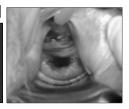
- generous hydrodissection
- transverse incisions careful tissue handling
- full-thickness dissection
- avoid button holes, trocar injury avoid incision over the vaginal cuff
- avoid concomitant hysterectomy avoid redundancy of mesh, no tension
- proper incision closure
- do not excise redundant vaginal wall

Terlecki RT and Flynn BJ: AUA update series 2010

Vaginal Wall Mesh Extrusion Initial Management

Initial Management

avoid heavy lifting antibiotics? aginal estrogen cal mesh excision or rimming" in clinic



Terlecki RT and Flynn BJ: AUA update series 2010

Vaginal Wall Mesh Extrusion Conservative Management

Retrospective review of the management of 4 vaginal wall mesh extrusions after SPARC sling in a single institution

- 2 patients presented with vaginal discharge 1 of which stated her partner had pain during intercourse

- To winch state her patine had pair uning intercourse 2 patients were asymptomatic
 Each patient was observed conservatively
 At 3 months postoperatively all 4 had complete spontaneous epithelialization over the mesh
 No patient developed had SUI, urgency or obstruction

Kobashi, KC and Govier, FE: J Urol 2003

"In my personal experience in management of more than 50 vaginal wall erosions I have seen only 1 erosion heal spontaneously."

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Vaginal Wall Mesh Extrusion Management in Prolapse Cases

Minor Extrusion (<8 weeks post-op)

- mesh non-redundant below plane of vaginal wall defect Vaginal estrogen Local mesh excision in clinic Pelvic rest, avoid heavy lifting

Large (> 2 cm), Recurrent Late Erosion (> 8 weeks)

- Excision of exposed mesh
- Raise 1 cm rim around exposed area
- Vigorous washout with bacitracin, betadine
- 2-layer closure (4-0 PDS running stitch, 4-0 PGA Mattress stitch
 - Consider alloderm for severe vaginal wall loss

Terlecki RT and Flynn BJ: AUA update series 2010

Urethral Erosion Prevention

Patient Selection

void the use of mesh in patients with XRT, infected field, neurogenics, diverticulum Occlusive slings

Urethra obstruction

Postop

Do not delay urethrolysis Avoid urethral dilation

Terlecki RT and Flynn BJ: AUA update series 2010

Urinary Tract Sling Erosion

Urethrolysis: Contemporary Outcomes

Study	No.	Туре	Management	Outcome
Kobashi et al 1999	7/34	ProteGen	Sling removal Martius (4) Delayed PVS (6)	25/34 (74%) SUI
Clemens et al 2000	6/14	ProteGen	Sling removal Urethral repair or prolonged drainage Immediate PVS (1) Delayed PVS (1)	5/6 (83%) SUI
Golomb et al 2001	1/1	Autograft	Bilateral partial excision	1/1 Dry
Amundsen et al 2003	6/6 3/3	Nonsynthetic Synthetic	Sling incision Sling removal Martius (2) Delayed PVS (1)	6/6 Dry 2/3 (67%) SUI

Polypropylene Bladder Erosion Prevention/Diagnosis

Prevention

roid tunneling the trocar if the retropubic space is scarred culous intra-op cystoscopy (70° lens), inspect anter wall at 2 and 11 o'clock op Foley for 3 days if bladder is perforated

Diagnosis



Hematuria, bladder pain, urgency, recurrent incontinence, adherent calculus to the bladder wall

Terlecki RT and Flynn BJ: AUA update series 2010

Polypropylene Bladder Erosion Case Reports: Endoscopic Approach

Endoscopic Laser Excision

3 patients had bladder erosion due to polyproplyene mesh Eroded tape successfully excised, 355 µm holmium laser in 20 mins

Suprapubic Assisted Endoscopic Excision †

- 1 patient underwent successful endoscopic excision 5 mm suprapubic trocar, 24 Fr transurethral nephroscope
- Forceps inserted through the trocar used to stretch the tape
- Endoscopic scissors inserted through the nephroscope used to excise the tape

† Jorion, JL: J Urol 2002

Perspectives in Urology 2009

Management of Urinary Tract Erosions Synthetic Erosion

Combined Abdominal and Vaginal Explantation *

- 5 patients with polypropylene mesh erosion
 - 3 with urinary tract erosion underwent explantation <u>ALL</u> required subsequent anti-incontinence surgery

Sweat SD, McGuire EJ and Lightner DJ: J Urol 2002

Mesh Explantation and Concomitant Sling †

- 19 patients with polypropylene mesh erosion underwent explantation
- 53% had recurrent SUI
- ıs autologous or porcine dermis sling

† Starkman, JS, et al : J Urol 2006

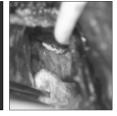


Institutional Sling Extrusion Data April 2003-Present

Vaginal Wall extrusion and urinary tract erosion

Vaginal wall extrusion/pain
retropubic tape 1 of 72 (1.4%)
TVT-0, 4 of 190 (2.1%)
TVT-S, 1 of 119 (0.8%)
Biological PVS, 0 of 60
AUS, 0 of 9

- Viriany tract erosion
 retropubic tape 1 of 72 (1.4%)
 TVT-O, 1 of 190 (0.5%)
 TVT-S, 0 of 119
 Biological PVS, 0 of 60
 AUS, 0 of 9



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2010 SUFU Abstract: MANAGEMENT OF POLYPROPYLENE MESH COMPLICATIONS (VAGINAL WALL EXTRUSIONS AND URINARY TRACT EROSIONS) AFTER SURGERY FOR SUI AND POP

39 patients that underwent mesh explantation due to recurrent vaginal wall extrusions and/or urinary tract erosions performed by BJF (2003-2009) were analyzed

treatment based upon CU algorithm for mesh complications patients classified as "simple" or "complex" graft complication simple graft complications treatment

- in office partial mesh excision
- OR excision, washout, and primary closure

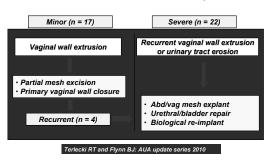
complex graft complications treatment

near total mesh excision, washout, repair of the urinary tract/vaginal wall, and concomitant placement of biological graft

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Polypropylene Mesh Complication Algorithm Location and Severity



Polypropylene Mesh Complication Algorithm

Operative Technique for Severe Graft Complication

bdominal/vaginal removal of

- mesh straps total explant of retropubic tapes, mini-slings removal of vaginal portion of TOT, prolapse mesh Urinary tract repair
- Biological re-implant · autologous RF PVS for slings · alloderm for prolapse kits 12 Fr foley (10-14 days) if urinary tract erosion



* Flynn BJ et al: SUFU 2010



Salvage Protocol

Near Total Mesh Explant, Washout, Re-implant with Biological

Step 1: EUA, cysto, DRE, procto, CT scan in complex cases Step 2: Remove eroded mesh with 1 cm ring of vaginal epithelium Step 3: Complex cases continue explanting remaining body of the vaginal mesh Step 4: Repair defects in the viscera, consider flap if a fistula is present Step 5: Cysto to asses repair, r/o urreteral injury or residual FB

Step 6: Irrigate with four solutions

bacitracin 50,000 units

gentamicin 80 mg in 1 l of 0.9% NS

's strength povidine-lodine, (500 ml)

's strength H202 (500 ml)

vancomycin 1 gm and gentamcin 80 mg, in 1 liter of 0.9% NS

Step 7: Change gowns and gloves

Step 8: Implant biological material

Step 9: Close wound in 2 layers

Step 10: Premarin vaginal pack Step 11: Treat with oral abx (based on culture results) for 1 month

Terlecki RT and Flynn BJ: AUA update series 2010

Management of Mesh Complications: Vaginal Wall Extrusions and Urinary Tract Erosions Results

Convalescence

mean f/u, 14 mos. mean age, 55.5 yrs mean length of stay · simple <23 hrs · complex 2.4 days Graft Complication Resolution

Simple group, n = 17

trimming, n = 4

1 of 4 (25%) successful

OR excision/reclosure, n = 13

12 of 13 (92%) successful

Complex group, n = 22

21 of 22 (95%) successful

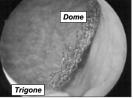
* Flynn BJ et al: SUFU 2010

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Management of Mesh Complications: Vaginal Wall Extrusions and Urinary Tract Erosions Continence Outcome

Post-operative 30 patients with data

regarding pad usage 25 of 30 (83%) dry, 0 ppd 3 required sling lysis for prolonged retention 1 required prolapse repair 1 required urethroplasty 1 required Interstim for UUI



* Flynn BJ et al: SUFU 2010

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Management of Vesicovaginal Fistula (VVF)

Transvaginal Repair of Primary and Recurrent Vesicovaginal Fistula (VVF)

Introduction

Terlecki RT and Flynn BJ et al: AUGS 2009

Transabdominal management often with the use of flaps, has been advocated for recurrent fistulae It is our practice to approach all nonirradiated primary or recurrent, VVFs via a transvaginal approach on an outpatient basis and to avoid the morbidity of a Martius flap

We aim to evaluate and compare the outcomes of transvaginal management of primary versus recurrent VVFs

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Transvaginal Repair of Primary and Recurrent Vesicovaginal Fistula (VVF)

Terlecki RT and Flynn BJ et al: AUGS 2009

31 cases (16 primary, 15 recurrent) of transvaginal VVF repair with cuff excision performed by a BJF (2002-2008) was analyzed

Etiology

open abdominal hysterectomy (23)

laparoscopic hysterectomy (2)

robotic hysterectomy (2),

transvaginal hysterectomy (2) mesh explant (1)

obstetric trauma (1)

18 prior repairs in 15 recurrent cases all at outside centers · 12 by a transvaginal approach and 6 transabominally

Transvaginal Repair of Primary and Recurrent Vesicovaginal Fistula (VVF)

Results

Parameter	Primary Repair	Secondary Repair
Patients (#)	16	15
Mean age (years)	12	42
Mean time to repair (days)	173	237
Mean fistula size (mm)	4./	3.6
Mean BMI (kg/m²)	30.8	28.8
Mean operative time (min)	157	143
Mean EBL (cc)	108	140
Mean LOS (days)	0.5*	0.1**
Mean catheterization (days)	22	21
Recurrence	0/16	0/15
Mean follow up (months)	25	30

Terlecki RT and Flynn BJ et al: AUGS 2009

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Transvaginal Repair of Primary and Recurrent Vesicovaginal Fistula (VVF) Results

Outcome

No significant differences between the treatment groups in any of the measured parameters

No operative complications occurred in either group Dyspareunia limited to 3 patients from the primary group At a f/u of 25 (primary) and 30 (recurrent) months, no patient has had a fistula recurrence

Convalescence

5 patients observed less than 24 hours (3 social, 2 pain) 1 patient observed less than 24 hours (social)