
UROLOGICAL SURVEY

Athanase Billis

State University of Campinas
Campinas, SP, Brazil

Andreas Böhle

Helios Agnes Karll Hospital
Bad Schwartau, Germany

Sean P. Elliott

University of Minnesota
Minneapolis, MN, USA

Fernando J. Kim

Univ Colorado Health Sci Ctr
Denver, Colorado, USA

Ricardo Miyaoka

State University of Campinas
Campinas, SP, Brazil

Manoj Monga

University of Minnesota
Edina, MN, USA

Adilson Prado

Vera Cruz Hospital
Campinas, SP, Brazil

Leonardo O. Reis

State University of Campinas
Campinas, SP, Brazil

M. Chad Wallis

University of Utah
Salt Lake City, Utah, USA

STONE DISEASE

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The digital flexible ureteroscope: in vitro assessment of optical characteristics

Zilberman DE, Lipkin ME, Ferrandino MN, Simmons WN, Mancini JG, Raymundo ME, Zhong P, Preminger GM

Division of Urologic Surgery, Comprehensive Kidney Stone Center, Duke University Medical Center, Durham, North Carolina 27710, USA

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Introduction: Recent advances in endoscope design have placed the charged coupled device chip on the tip of the endoscope. The image is instantly digitalized and converted into an electrical signal for transmission. Digital technology was first introduced into flexible cystoscopes/nephroscopes and subsequently into rigid and flexible ureteroscopes. Herein, we assess the image characteristics and advantages of a new generation of digital flexible ureteroscopes.

Methods: The Olympus URF-V flexible digital ureteroscope and the Olympus URF-P3 fiberoptic ureteroscope were assessed in vitro for image resolution, distortion, color representation, grayscale imaging, field of view, and depth of field.

Results: The digital ureteroscope had a higher resolution at 3, 5, 10, and 20 mm (25.2 lines/mm vs. 8.0, 14.1 vs. 5.0, 6.3 vs. 2.8, and 3.2 vs. 1.3), respectively. Distortion with the digital flexible ureteroscope was lower, though not statistically significant. Color representation was better with the digital ureteroscope, whereas contrast evaluation was comparable between both scopes. The digital flexible ureteroscope produced a 5.3 times larger image size compared with the standard fiberoptic flexible ureterscope with a narrower field of view. The depth of field was limited by light and not the optic or the camera for both ureteroscopes.

Conclusions: The development of digital flexible ureteroscopes represents a significant technological advance in urology. These devices offer significantly improved resolution and color reproduction as compared with traditional fiberoptic flexible ureteroscopes. Future clinical trials are warranted to ultimately determine the advantages of these innovative endoscopes.

Editorial Comment

The authors conducted a comprehensive evaluation of a new digital flexible ureteroscope, however unfortunately they compared it to an old-generation fiberoptic scope - the URF-P3; it would have been preferable to evaluate the latest generation fiberoptic scope, the URF-P5. Despite this limitation, they noted some significant differences, and some significant similarities between the two scopes. Both modalities provided good image contrast and minimal distortion, as well as good color representation and depth of field. While image quality (resolution, image size) was superior with the digital scopes, certain characteristics that may impact ease of maneuvering and navigating (small scope size, larger field of view) was superior for the fiberoptic scope. The relative value of improved resolution and larger image (digital scopes) compared to the relative value of a larger field of view and smaller scope size (fiberoptic scopes) warrants a clinical trial. 8.5F at the tip.

Dr. Manoj Monga

*Director, Stevan B. Strem Center for
Endourology & Stone Disease
Glickman Urological & Kidney Institute
The Cleveland Clinic
Cleveland, Ohio, USA
E-mail: endourol@yahoo.com*

A comparison of treatment modalities for renal calculi between 100 and 300 mm²: are shockwave lithotripsy, ureteroscopy, and percutaneous nephrolithotomy equivalent?

Wiesenthal JD, Ghiculete D, D'A Honey RJ, Pace KT

Division of Urology, Department of Surgery, St. Michael's Hospital, University of Toronto, Toronto, Ontario, Canada

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Background and Purpose: Shockwave lithotripsy (SWL) is considered a standard treatment for patients with upper-tract stones that are less than 10 mm in diameter, whereas stones that are larger than 20 mm are best managed by percutaneous nephrolithotomy (PCNL). The management of stones between these sizes remains controversial. Our purpose was to review our contemporary series of SWL, ureteroscopy (URS), and PCNL outcomes for intermediate-sized upper tract calculi (100-300 mm²).

Patients and Methods: Analysis was restricted to those patients who were treated for a renal calculus that measured between 100 and 300 mm² during a 4-year span. Demographic, stone, patient, treatment, and follow-up data were collected from a prospectively maintained database.

Results: A total of 137 patients were referred with nonstaghorn calculi with an area between 100 and 300 mm². Fifty-three (38.7%) patients were treated with SWL, while 41 (29.9%) and 43 (31.4%) underwent ureteroscopy and PCNL, respectively. Mean stone area was higher in the PCNL group ($P < 0.001$), whereas stone density was higher for patients undergoing SWL ($P = 0.002$). Single treatment success rates were better for PCNL at 95.3%, vs 87.8% for ureteroscopy and 60.4% for SWL, $P < 0.001$. When allowing for two SWL treatments, the success rate improved to 79.2%, thus equalizing the success of the three treatment modalities ($P = 0.66$). Auxiliary treatments were more common after SWL (42.3%; $P < 0.01$).

Conclusions: For intermediate-sized upper-tract stones, when allowing for up to two SWL treatments, there was no significant difference between treatment modalities. Thus, SWL is a reasonably successful treatment alternative for patients who are not fit for a general anesthetic or who prefer SWL over competing treatments, provided they accept a potentially higher number of treatments.

Editorial Comment

This study has significant limitations. Selection bias may impact choice of treatment. The authors state that stone characteristics impacted selection of treatment modality, yet they do not elaborate on what characteristics were considered or how they impacted the decision tree. Stone density was higher in the SWL group, while stone size was larger in the PCNL group. Post-operative imaging modality was not standardized. Different definitions for success were used between the three groups; with a more stringent definition for PCNL, and liberal definition for URS and SWL. The authors correctly note that the higher retreatment rates with SWL may be counter-balanced by the lower hospitalization rate, length of stay and need for ureteral stents. They appropriately conclude that the final choice of treatment depends on the patient preference, clinical scenario, and available equipment and expertise.

Dr. Manoj Monga

*Director, Stevan B. Strem Center for
Endourology & Stone Disease
Glickman Urological & Kidney Institute
The Cleveland Clinic
Cleveland, Ohio, USA
E-mail: endourol@yahoo.com*

ENDOUROLOGY & LAPAROSCOPY

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Complications and conversions of upper tract urological laparoendoscopic single-site surgery (less): multicentre experience: results from the NOTES Working Group

Irwin BH, Cadeddu JA, Tracy CR, Kim FJ, Molina WR, Rane A, Sundaram CP, Raybourn Iii JH, Stein RJ, Gill IS, Kavoussi LR, Richstone L, Desai MM

Glickman Urological and Kidney Institute, Cleveland, OH, University of Texas Southwestern Medical Center, Dallas, TX Tony Grampas Cancer Center, University of Colorado Health Sciences Center, Denver, CO Indiana University, Indianapolis, IN The Smith Institute for Urology, The North-Shore Long Island Jewish Health System, New York, NY, USA East Surrey Hospital, Redhill, UK

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Study Type - Therapy (case series) Level of Evidence 4

Objective: To present complications and rates of conversion from LESS to conventional laparoscopy (CL) at the time of upper tract LESS urologic procedures.

Patients and Methods: Patients undergoing LESS upper tract procedures between September, 2007 and November, 2008 (n = 125) were identified at six high-volume academic centers pioneering urologic LESS procedures. All LESS procedures were performed transperitoneally via a single umbilical incision using either adjacent conventional trocars or a dedicated single-site access device. Reconstructive procedures incorporating a single planned 2mm accessory needle port were included as LESS procedures and were not considered conversions. Patients, undergoing LESS procedures requiring conversion to CL with the placement of additional ports were identified. Conversion was defined as the placement of additional 5 or 10/12mm ports beyond the primary incision. In each case the operative reports were reviewed, the reason for conversion was determined, and the number and types of additional ports and complications were noted.

Results: Upper tract LESS procedures were performed in 125 patients comprising 13.3% of the total 937 laparoscopic procedures performed at the participating institutions during this time period. Conversion to CL was necessary in 7 patients (5.6%) undergoing LESS requiring the addition of 2-5 ports. Reasons for conversion included: facilitate dissection in 3 (43%), facilitate reconstruction in 3 (43%), and control of bleeding in 1 (14%). All attempted LESS cases were completed laparoscopically without need for open conversion. Complications occurred in 15.2% of patients undergoing LESS surgery. Three of the 7 patients that required conversion to CL developed postoperative complications (Clavien grade II in two and IIIa in one). Limitations of this study included the inability to standardize LESS patient selection criteria, instrumentation and surgical technique as well as the lack of available complete data from a CL control group for comparison.

Conclusion: LESS surgery is technically feasible for a variety of upper urinary tract reconstructive and ablative procedures, although it appears to be associated with higher rates of complications than in mature CL series. Conversion to CL occurs infrequently and may be a reflection of stringent patient selection.

Editorial Comment

The authors present a multi-center study on patients undergoing LESS upper tract procedures between September, 2007 and November, 2008 (n = 125). A total of 6 high-volume academic centers pioneering urologic LESS procedures were identified and participated in the study. Since the first laparoscopic procedure was performed the objective of ultimate less tissue damage and faster recovery of patients with optimal cosmetic results have been the "holy grail" of minimally invasive surgery. From a total of 937 Laparoscopic 77 (8.2%) had upper tract urological procedures, 125 underwent LESS, 7.8%, 48 (5.1%) Extirpative/Ablative LESS

Procedures with Complication rates of had reconstructive LESS Procedures with complication rates of 27.1%. The authors completed LESS Extirpative/Ablative Procedures in 74 patients with complication 6.7%. Three (0.3%) were converted to conventional laparoscopy with rates of complication rates of 33%. In the reconstructive LESS Procedures 44 patients had completion of surgery while conversion to conventional laparoscopic surgery rate was 0.4%. It is important to note that these are highly skill surgeons from high volume centers. Overall, the LESS procedures seem to be the next step to create new platforms and instrumentations to better serve our patients with less invasive techniques.

Dr. Fernando J. Kim

*Chief of Urology, Denver Health Med. Ctr.
Associate Professor, Univ. Colorado Health Sci. Ctr.
Director of Minimally Invasive Urol. Oncology, UCHSC
Denver, Colorado, USA
E-mail: fernando.kim@dhha.org*

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Living donor kidney transplantation with multiple renal arteries in the laparoscopic era

Tyson MD, Castle EP, Ko EY, Andrews PE, Heilman RL, Mekeel KL, Moss AA, Mulligan DC, Reddy KS
Department of Urology, Mayo Clinic, Phoenix, Arizona; Department of Urology, Mayo Clinic, Phoenix, Arizona

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Objectives: To compare the postoperative complications and survival metrics after multiple renal arteries (MRA) and single renal artery (SRA) laparoscopically procured living donor kidney transplantation (LLDKT). MRA are the most frequently encountered anatomic variation during kidney transplantation. The long-term outcomes of LLDKT with MRA are not well characterized.

Methods: A retrospective review of our institution's LLDKT database was performed. All surgeries were performed at a single tertiary care academic center between June 1999 and September 2008. Patients were divided into 2 cohorts (MRA vs. SRA), and analysis was limited to patients with at least 1-year follow-up.

Results: Of 584 LLDKTs, 510 had at least 1-year follow-up (median: 36 months). A total of 393 grafts had an SRA, whereas 117 (23%) had MRA. When complications were stratified by the Clavien classification system, no differences were noted between groups ($P = .5$). Furthermore, rates of vascular ($P = .2$) and urological ($P = .9$) complications were similar between groups. There was, however, a higher incidence of slow graft function in the MRA group ($P = .01$), despite similar rates of delayed graft function ($P = .9$) and acute rejection ($P = .4$). Furthermore, allograft survival was similar between both groups with 76% of MRA and 81% of SRA grafts functioning at 5 years ($P = .49$). Patient overall survival was likewise similar between groups with 88% of MRA and 86% of SRA recipients surviving at 5 years ($P = .76$).

Conclusions: Despite a higher incidence slow graft function, MRA in LLDKT does not adversely affect long-term allograft and patient overall survival.

Editorial Comment

The authors compared the postoperative complications and survival metrics after multiple renal arteries (MRA) and single renal artery (SRA) laparoscopically procured living donor kidney transplantation (LLDKT). The advances of minimally invasive surgery after the pioneer work of Kavoussi et al. transcends biases limitations that we never imagine would be possible to transpose.

The challenges of procuring a kidney with multiple renal arteries is a difficult task even to open surgeons, while laparoscopically it became a reality and this report reveals a higher incidence of slow graft function in recipients of allografts with multiple renal arteries but the multiplicity of renal arteries in laparoscopically procured living donor kidney transplantation does not adversely affect 5-year allograft and patient overall survival.

Dr. Fernando J. Kim

Chief of Urology, Denver Health Med. Ctr.

Associate Professor, Univ. Colorado Health Sci. Ctr.

Director of Minimally Invasive Urol. Oncology, UCHSC

Denver, Colorado, USA

E-mail: fernando.kim@dhha.org

IMAGING

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Comparison of CT Urography and Excretory Urography in the Detection and Localization of Urothelial Carcinoma of the Upper Urinary Tract

Jinzaki M, Matsumoto K, Kikuchi E, Sato K, Horiguchi Y, Nishiwaki Y, Silverman SG

Department of Diagnostic Radiology, Keio University School of Medicine, 35 Shinanomachi, Shinjuku-ku, Tokyo 160-8582, Japan

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Objective: The purpose of this study was to compare the accuracy of CT urography and excretory urography for the detection and localization of upper urinary tract urothelial carcinoma.

Materials and Methods: Of 128 patients at high risk for upper tract urothelial carcinoma who were examined with both CT urography and excretory urography between 2002 and 2007, 24 were undiagnosed and excluded. CT urography and excretory urography results of the remaining 104 patients and 552 urinary tract segments were compared with histopathologic examination or follow-up imaging at 1 year. Two readers independently scored the confidence levels for the presence or absence of upper urinary tract urothelial carcinoma in each of six upper urinary tract segments on both CT urography and excretory urography; differences were resolved by consensus.

Results: Upper urinary tract urothelial carcinoma was diagnosed in 77 (14%) segments of 46 (44%) patients. Per-patient sensitivity, specificity, overall accuracy, and area under the receiver operating characteristic curves for detecting carcinomas with CT urography (93.5% [43/46], 94.8% [55/58], 94.2% [98/104], and 0.963, respectively) were significantly greater than those for excretory urography (80.4% [37/46], 81.0% [47/58], 80.8% [84/104], and 0.831, respectively) ($p = 0.041$, $p = 0.027$, $p = 0.001$, and $p < 0.001$, respectively). Per-segment sensitivity and overall accuracy for the localization of upper urinary tract urothelial carcinoma were significantly greater with CT urography (87.0% [67/77] and 97.8% [540/552]) than with excretory urography (41.6% [32/77] and 91.5% [505/552]) ($p < 0.0001$).

Conclusion: CT urography was more accurate than excretory urography in the detection and localization of upper urinary tract urothelial carcinoma and should be considered as the initial examination for the evaluation of patients at high risk for upper urinary tract urothelial carcinoma.

Editorial Comment

This is a retrospective study looking at the accuracy of CT urography compared to excretory urography (EU) for the detection and localization of urothelial carcinoma of the upper urinary tract. The authors enrolled 104 patients in the study all of whom at risk for pelvocalyceal cancer. Their results show that the accuracy of CT urography for both the detection and localization of upper urinary tract urothelial carcinoma was significantly better than that of excretory urography. CT urography was superior particularly to detect small (< 15 mm) masses, usually hidden by contrast material or obscured by gas on EU. CT urography was able to detect tumor in obstructed and unopacified kidney. The main limitations of CT urography, were the incapacity of distinguish between inflammatory and cancerous pelvocalyceal wall thickening; incapacity to detect CIS or localize superficial extension of the tumor and to localize multiple papillary tumors smaller than 10 mm within unopacified collapsed segments.

In our experience differentiation between inflammatory and cancerous focal thickening of the pelvocalyceal system wall can be very difficult. Presence of endothelial irregularities, invasion of local tissue, obliteration of local fat plane and contrast enhancing are features characteristic of tumor. In the absence of these findings however, endoscopy with biopsy is mandatory for the differential diagnosis.

Evidence is growing that in near future, an optimized CT-urography protocol, will replace EU for the evaluation of hematuria and follow-up of patients at risk for urothelial cancer.

Dr. Adilson Prando

*Head, Department of Radiology and
Diagnostic Imaging, Vera Cruz Hospital
Campinas, São Paulo, Brazil
E-mail: adilson.prando@gmail.com*

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Areas suspicious for prostate cancer: MR-guided biopsy in patients with at least one transrectal US-guided biopsy with a negative finding-multiparametric MR imaging for detection and biopsy planning

Franiel T, Stephan C, Erbersdobler A, Dietz E, Maxeiner A, Hell N, Huppertz A, Miller K, Strecker R, Hamm B

*Department of Radiology, Charité-Universitätsmedizin Berlin, Charitéplatz 1, 10117 Berlin, Germany
Radiology. 2011;259:162-72*

Purpose: To prospectively investigate the incremental value of multiparametric magnetic resonance (MR) imaging compared with standard T2-weighted imaging for biopsy planning.

Materials and Methods: The study was approved by the institutional review board; informed consent was obtained. Consecutive patients underwent T2-weighted imaging supplemented with multiparametric 1.5-T MR imaging, consisting of hydrogen 1 ((1)H) MR spectroscopy, diffusion-weighted (DW) imaging, and contrast material-enhanced MR imaging. Quantitative parameters were calculated: (choline plus creatine)-to-citrate ratio, apparent diffusion coefficient, and volume transfer constant and exchange rate constant. The prostate was divided into 20 standardized areas. Each area was classified as benign, inconclusive, or suspicious at T2-weighted imaging, followed by quantitative evaluation of all inconclusive and suspicious areas with multiparametric MR imaging. MR-guided biopsy was performed in lesions classified as suspicious for cancer with at least one of the techniques after transfer to three-dimensional T2-weighted images. Diagnostic parameters were calculated on a per-lesion and per-patient basis for all combinations of T2-weighted imaging with multiparametric MR imaging.

Results: Fifty-four patients had a median of two prior transrectal ultrasonographic biopsies with negative findings. Each patient had a median of three suspicious lesions. Prostate cancer was demonstrated in 21 of 54 patients. Biopsy was performed in 178 lesions; 53 were positive for prostate cancer. Detection rates and test negative results, respectively, were as follows: T2-weighted imaging, 70% and 50%; T2-weighted imaging and (1)H MR spectroscopy, 81% and 32%; T2-weighted imaging and contrast-enhanced MR imaging, 83% and 29%; T2-weighted imaging and DW imaging, 85% and 30%; T2-weighted imaging, (1)H MR spectroscopy, and contrast-enhanced MR imaging, 91% and 13%; T2-weighted imaging, (1)H MR spectroscopy, and DW imaging, 94% and 15%; T2-weighted imaging, DW imaging, and contrast-enhanced MR imaging, 94% and 13%; T2-weighted imaging, (1)H MR spectroscopy, DW imaging, and contrast-enhanced MR imaging, 100% and 0%.

Conclusion: Only the combination of T2-weighted imaging with all three multiparametric techniques depicts all identifiable prostate cancers; a double combination with DW imaging and (1)H MR spectroscopy or contrast-enhanced MR imaging misses 6%, while reasonably reducing the number of areas needing biopsy.

Editorial Comment

This is a prospective study looking at the incremental value of multiparametric MR imaging representing the integration of spectroscopy (MRSI), diffusion-weighted imaging (DWI) and dynamic-contrast enhanced MR imaging (DCE) in comparison with conventional T2-weighted imaging for the detection of prostate cancer. The authors enrolled 54 patients with at least one negative transrectal US-guided prostate biopsy and elevated or rising PSA. Their results show that in this selected group of patients MRI-guided biopsy oriented by findings obtained with the combinations of T2-weighted imaging, DWI, and DCE and T2-weighted imaging, MRSI and DWI depicted cancer in 21 out 54 patients (39%) representing 94% of all prostate cancer areas (19% higher than if biopsy were oriented by the results of anyone isolated technique).

Recently several methods have been used to orient the rebiopsy of prostate based on suspicious areas of cancer found in multiparametric MR imaging. In our institution, suspicious areas detected on multiparametric MRI have been sampled by transrectal US-guided biopsy. Since 2004 we have been using a visual method of overlaying suspicious multiparametric MRI findings onto axial US scans (1). Internal and external prostatic and periprostatic anatomic landmarks are used to project suspicious MRI findings on US scans. Our method has limitations since demands high level of expertise in prostate imaging. Recently however electronic real-time fusion of endorectal MR images with endorectal US images and the use of specially designed MRI-guided biopsy device, have been implemented and this task has been facilitated as shown by the authors of this manuscript. However in any of these circumstances, a close relationship between radiologist and urologist is mandatory.

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Dr. Adilson Prando
Head, Department of Radiology and
Diagnostic Imaging, Vera Cruz Hospital
Campinas, São Paulo, Brazil
E-mail: adilson.prando@gmail.com

PATHOLOGY

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The Contemporary Concept of Significant Versus Insignificant Prostate Cancer

Ploussard G, Epstein JI, Montironi R, Carroll PR, Wirth M, Grimm MO, Bjartell AS, Montorsi F, Freedland SJ, Erbersdobler A, van der Kwast TH

Department of Urology, Saint-Louis Hospital, APHP, Paris, France; INSERM 955, Team 7, University Paris 12, Créteil, France

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Context: The notion of insignificant prostate cancer (Ins-PCa) has progressively emerged in the past two decades. The clinical relevance of such a definition was based on the fact that low-grade, small-volume, and organ-confined prostate cancer (PCa) may be indolent and unlikely to progress to biologic significance in the absence of treatment.

Objective: To review the definition of Ins-PCa, its incidence, and the clinical impact of Ins-PCa on the contemporary management of PCa.

Evidence Acquisition: A review of the literature was performed using the Medline, Scopus, and Web of Science databases with no restriction on language up to September 2010. The literature search used the following terms: insignificant, indolent, minute, microfocal, minimal, low volume, low risk, and prostate cancer.

Evidence Synthesis: The most commonly used criteria to define Ins-PCa are based on the pathologic assessment of the radical prostatectomy specimen: (1) Gleason score ≤ 6 without Gleason pattern 4 or 5, (2) organ-confined disease, and (3) tumour volume $< 0.5\text{cm}^3$. Several preoperative criteria and prognostication tools for predicting Ins-PCa have been suggested. Nomograms are best placed to estimate the risk of progression on an individualised basis, but a substantial proportion of men with a high probability of harbouring Ins-PCa are at risk for pathologic understaging and/or undergrading. Thus, there is an ongoing need for identifying novel and more accurate predictors of Ins-PCa to improve the distinction between insignificant versus significant disease and thus to promote the adequate management of PCa patients at low risk for progression.

Conclusions: The exciting challenge of obtaining the pretreatment diagnostic tools that can really distinguish insignificant from significant PCa should be one of the main objectives of urologists in the following years to decrease the risk of overtreatment of Ins-PCa.

Editorial Comment

With screening for prostate carcinoma, an increasing number of small tumors have been diagnosed. These small tumors may be indolent and unlikely to progress to biologic significance in the absence of treatment. In the past two decades criteria based on needle biopsies have emerged to identify tumors that may behave as indolent (insignificant). The criteria are based on pathologic findings of the radical prostatectomy specimen.

The most used criteria to define insignificant cancer on needle biopsy were proposed by Epstein: 1. no more than 2 cores with carcinoma; 2. no more than 50% of extent on any core; 3. no Gleason pattern 4 or 5; 4. PSA density < 0.15 ; and, 5. clinical stage T1c. A contemporary analysis found that 84% of patients satisfying these criteria, showed organ-confined disease and Gleason score < 6 without Gleason pattern 4 or 5 on the surgical specimen (1).

Other studies, however, found a less predictive value for insignificant cancer on radical prostatectomies using Epstein's criteria: 76%, 69% and 54% from Europe (Germany), Asia (South Korea), and Middle East (Egypt), respectively (2-4). Obviously, racial, environmental, alimentary and methodological

factors may be involved in these discrepancies.

Due to the relevance of identifying patients harboring indolent tumors, the authors emphasize the need for identifying novel and more accurate predictors of insignificant cancer to improve the distinction between insignificant versus significant disease and thus to promote the adequate management of prostate cancer patients at low risk for progression.

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Dr. Athanase Billis

Full-Professor of Pathology

State University of Campinas, Unicamp

Campinas, São Paulo, Brazil

E-mail: athanase@fcm.unicamp.br

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Treatment decision-making for localized prostate cancer: What younger men choose and why

Sidana A, Hernandez DJ, Feng Z, Partin AW, Trock BJ, Saha S, Epstein JI
Department of Urology, The Johns Hopkins Hospital, Baltimore, Maryland
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Background and Objective: The literature lacks knowledge about information preferences and decision-making in young prostate cancer patients. This study provides insight into information sources consulted and factors dictating treatment decision-making in young prostate cancer patients.

Methods: Subjects were identified from pathology consult service of a National Center of Excellence. Questionnaires were mailed to 986 men, under 50 years of age, diagnosed with Gleason score 6 prostate cancer between 2001 and 2005.

Results: Four hundred ninety-three men responded. The most common primary therapies were surgery 397 (81.4%), radiation 52 (10.7%), and active surveillance (AS) 26 (5.3%). Participants with at least some college education ($P = 0.003$) or annual income $> \$100,000$ ($P = 0.003$) were more likely to consult three or more doctors. Amongst all treatments, “doctor’s recommendation” was the most influential information source, although relatively less important in the AS group. Internet was the second most frequent information source. Participants with higher education ($P = 0.0003$) and higher income ($P = 0.002$) considered sexual function more important while making a treatment choice. Only 2% of the men preferred a passive role in the decision-making. Informed decision-making was preferred more by patients who chose radiation and AS while shared decision-making was preferred more by surgery patients ($P < 0.05$). The majority (89%) of the respondents did not regret their decision. No difference in satisfaction levels was found between different treatment modalities.

Conclusions: This study provides insight into information sources consulted, such as the greater internet use, and various factors dictating treatment decision-making in young prostate cancer patients. There was an overall very high satisfaction rate regardless of the therapy chosen.

Editorial Comment

This is an interesting survey from the Johns Hopkins. Four hundred ninety-three men under 50 years diagnosed with Gleason score 6 prostate cancer answered a questionnaire related to type of therapy. The most common primary therapy was surgery 397 (81.4%), followed by radiation 52 (10.7%), and active surveillance 26 (5.3%) patients.

Interesting findings include: 1. Participants with some college education or higher annual income were more likely to consult 3 or more doctors; 2. Amongst all types of treatment “doctor’s recommendation” was the most influential information source; 3. Internet was the second most frequent information source; 4. Participants with higher education and higher income considered sexual function more important while making a treatment choice; 5. Only 2% of the men preferred a passive role in the decision-making; and, 6. Informed decision-making was preferred more by patients who chose radiation and active surveillance while shared decision-making was preferred more by surgery patients.

The study provided insight into information sources consulted, such as the greater internet use, and various factors dictating treatment decision-making in young prostate cancer patients.

Dr. Athanase Billis

Full-Professor of Pathology

State University of Campinas, Unicamp

Campinas, São Paulo, Brazil

E-mail: athanase@fcm.unicamp.br

RECONSTRUCTIVE UROLOGY

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Management of Adult Anterior Urethral Stricture Disease: Nationwide Survey Among Urologists in The Netherlands

van Leeuwen MA, Brandenburg JJ, Kok ET, Vijverberg PL, Bosch JL

Department of Urology, University Medical Centre Utrecht, Utrecht, The Netherlands

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Background: Adult anterior urethral stricture disease is most often treated with dilatation or direct vision internal urethrotomy (DVIU). Although evidence suggests that anastomotic urethroplasty for short bulbar strictures is more efficient and cost effective in the long term, no consensus exists. It is unclear by whom and how often urethroplasties are performed in The Netherlands and how results are being evaluated.

Objective: To determine national practice patterns on management of anterior urethral strictures among Dutch urologists. This information will help to define the nationwide need for training in urethral surgery.

Design, Setting, and Participants: We conducted a 16-question survey among all 323 Dutch urologists.

Results and Limitations: The response rate was 74%. DVIU was practised by 97% of urologists. Urethroplasty was performed at least once yearly by 23%, with 6% performing more than five urethroplasties annually. In the group of urologists younger than 50 yr of age, 13% performed urethroplasty, with 3% of those performing more than five annually. In the case of a 3.5-cm-long bulbar stricture, DVIU was preferred by 49% of responders. Even after two recurrences, 20% continued to manage a 1-cm-long bulbar stricture endoscopically. Of responders, 79% believed that urethroplasty should be proposed only after a failed endoscopic

attempt. Diagnostic workup and evaluation of success varied greatly.

Conclusions: Most Dutch urologists believe that urethroplasty is an option only after failed DVIU. Endoscopic procedures are widely used, even when the risk of recurrence is virtually 100%. The definition of success is hampered by nonstandardised methods of follow-up. Only a small group of mainly older urologists frequently performs urethroplasties. Training programmes seem necessary to guarantee a high standard of care for stricture disease in The Netherlands. A pan-European practice survey might be interesting to clarify the need for centralised fellowship programmes.

Editorial Comment

The authors describe the results of a survey distributed to Dutch urologists about their management of urethral stricture disease. Interestingly, these results are highly similar to a survey done of urologists in the United States a couple of years ago (1). Indeed, in both countries, the common perception is that internal urethrotomy or dilation is appropriate management of strictures that, based on currently available evidence, would be better treated with urethroplasty. Several series demonstrate that the success rate with urethral dilation or urethrotomy for strictures over 2cm or recurrent strictures is unacceptably low (2,3). Yet, rather than a misunderstanding about treatment effectiveness, these practice patterns may merely represent the reality that properly trained reconstructive urologists are not available in many parts of the world, even in highly industrialized countries like the Netherlands and U.S. Only 3% of urologists surveyed performed more than 5 urethroplasties a year. The argument in favor of training additional surgeons in these techniques is quite appropriate.

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Dr. Sean P. Elliott

*Department of Urology Surgery
University of Minnesota
Minneapolis, Minnesota, USA
E-mail: selliot@umn.edu*

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The Cleveland Clinic experience with adult hypospadias patients undergoing repair: their presentation and a new classification system

Ching CB, Wood HM, Ross JH, Gao T, Angermeier KW

Cleveland Clinic Foundation, Glickman Urological and Kidney Institute, Cleveland, OH, USA

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Objective: To characterize and categorize adults with hypospadias who presented to our clinic with urethral stricture and fistula to better clarify the presentation, history and intraoperative findings in this heterogeneous group and to better describe the natural history of this anomaly in adulthood.

Patient and Methods: A retrospective chart review was performed on adults with hypospadias who underwent urethroplasty for urethral stricture, urethrocuteaneous fistula, and/or hypospadias repair at Cleveland

Clinic between 1993 and 2009. All procedures were performed by a single staff surgeon (K.W.A.). The charts were reviewed for site of hypospadias, presenting complaint, overall symptoms, history of repair and type of surgery performed.

Results: Fifty-five adult patients were identified. Median age was 37 years (range: 18-72). About half of the patients had distal (glanular/subcoronal or pendulous) hypospadias (56.4%) and the others had more proximal (bulbar) hypospadias (43.6%). Voiding symptoms (such as dysuria, weak stream, spraying, urgency, frequency) were the most common presenting complaint (50.9%) and overall symptom (81.8%). About half of patients underwent a two-stage urethroplasty (52.7%). Based on their history of repair, patients were divided into three categories: I, patients who have undergone continuous multiple surgeries for repair with significant scarring and tissue loss; II, delayed complications after an initially successful childhood repair; and III, no previous repair. Most patients were category I (58.2%); however, seven patients (12.7%) were category III. Balanitis xerotica obliterans (BXO) was more common in this subgroup compared with other categories (42.9% vs 8.3%, respectively, $P = 0.037$). In two of the three patients in category III with BXO, the stricture length was longer than 7 cm.

Conclusions: Adults with hypospadias represent a heterogeneous group. More than half of adults with complications related to hypospadias have had multiple operations (category I) representing one of the most difficult challenges to the reconstructive urologist. Roughly 30% of patients undergo an initially successful repair in childhood with recurrent problems in adulthood (category II), suggesting that the outcomes of repair may not be as durable as estimated by studies with shorter-term follow-up. Finally, BXO is over-represented in men with hypospadias who have not previously undergone repair, which contradicts the previous suggestion that the risk of BXO is related to the use of skin grafts/flaps from previous repairs and suggests that there may be an increased risk of severe stricture disease in patients who have never undergone corrective surgery for this anomaly.

Editorial Comment

The take home messages from this article are that (1) repair of previously operated-upon adult hypospadias is extremely difficult and (2) failure of childhood hypospadias repair may be more frequent than we understand it to be based on pediatric surgical series in which the follow-up stops at or before adolescence. An additional insight covered briefly in the article is the psychological challenges faced by adult men with hypospadias complications. Some are bothered by a sense that their penis is different in appearance from their peers and seek additional surgery in pursuit of a “normal” penis. Here, the words of Voltaire are often appropriate counsel: “Le mieux est l’ennemi du bien”, or “The best is the enemy of the good”. It is ill-advised to pursue additional surgeries to correct a urethra that is free of stricture but has a mild sacculation that causes post-void dribbling. Similarly, whereas an orthotopic mid-glans meatus is the goal in pediatric hypospadias repair, a sub-coronal meatus is preferable in adult hypospadias reconstruction because the glansplasty is fraught with complications. Another psychological consideration is that some men with restenosis after childhood hypospadias repair approach any additional surgery with great anxiety and fear. Repeat surgery can bring up memories of suffering through repeat interventions as a child. Truly, these represent challenging patients, pre-operatively, intra-operatively and post-operatively. They require skilled attention and careful counseling.

Dr. Sean P. Elliott

Department of Urology Surgery

University of Minnesota

Minneapolis, Minnesota, USA

E-mail: selliot@umn.edu

Cancer control and functional outcomes after radical prostatectomy as markers of surgical quality: analysis of heterogeneity between surgeons at a single cancer center

Vickers A, Savage C, Bianco F, Mulhall J, Sandhu J, Guillonneau B, Cronin A, Scardino P

Department of Surgery, Memorial Sloan-Kettering Cancer Center, New York, NY 10021, USA

Eur Urol. 2011; 59: 317-22

Background: Previous studies have shown that complications and biochemical recurrence rates after radical prostatectomy (RP) vary between different surgeons to a greater extent than might be expected by chance. Data on urinary and erectile outcomes, however, are lacking.

Objective: In this study, we examined whether between-surgeon variation, known as heterogeneity, exists for urinary and erectile outcomes after RP.

Design, Setting, and Participants: Our study consisted of 1910 RP patients who were treated by 1 of 11 surgeons between January 1999 and July 2007.

Intervention: All patients underwent RP at Memorial Sloan-Kettering Cancer Center.

Measurements: Patients were evaluated for functional outcome 1 yr after surgery. Multivariable random effects models were used to evaluate the heterogeneity in erectile or urinary outcome between surgeons, after adjustment for case mix (age, prostate-specific antigen, pathologic stage and grade, comorbidities) and year of surgery.

Results and Limitations: We found significant heterogeneity in functional outcomes after RP ($p < 0.001$ for both urinary and erectile function). Four surgeons had adjusted rates of full continence $< 75\%$, whereas three had rates $> 85\%$. For erectile function, two surgeons in our series had adjusted rates $< 20\%$; another two had rates $> 45\%$. We found some evidence suggesting that surgeons' erectile and urinary outcomes were correlated. Contrary to the hypothesis that surgeons "trade off" functional outcomes and cancer control, better rates of functional preservation were associated with lower biochemical recurrence rates.

Conclusions: A patient's likelihood of recovering erectile and urinary function may differ depending on which of two surgeons performs his RP. Functional preservation does not appear to come at the expense of cancer control; rather, both are related to surgical quality.

Editorial Comment

Surgical volume or institutional volume is regarded as markers of quality and outcome in cancer surgery. Here, the authors show that within a single, high-volume institute large differences in cancer control and functional results exist between the 11 surgeons involved. Furthermore, in contrast to other available data which report incredible results of specialized centers the data presented here can be regarded as very honest. Overall, the mean adjusted proportion of patients with good erectile function at 1 year for all surgeons was 30% and the mean adjusted proportion of patients who were continent at 1 year for all surgeons was 80%. The adjusted rates of good erectile functions ranged from 8% to 49% and rates of continence ranged from 64% to 97%, showing large differences between surgeons. Interestingly, surgeons with better functional outcomes also had higher rates of cancer control.

In short, the surgeon matters, and not so much the institution.

Dr. Andreas Bohle

Professor of Urology

HELIOS Agnes Karll Hospital

Bad Schwartau, Germany

E-mail: boehle@urologie-bad-schwartau.de

Adverse renal outcomes in subjects undergoing nephrectomy for renal tumors: a population-based analysis

Klarenbach S, Moore RB, Chapman DW, Dong J, Braam B

Department of Medicine, Division of Nephrology and Immunology, University of Alberta, Edmonton, Alberta, Canada

Eur Urol. 2011; 59: 333-9

Background: There has been increasing interest in determining renal outcomes after nephrectomy for renal tumors. Previous studies have not assessed all relevant risk factors, including proteinuria.

Objective: We sought to determine the risk and predictors for the development of adverse renal outcomes in a population-based cohort of subjects undergoing partial or complete nephrectomy.

Design, Setting, and Participants: A large population-based data set was used to identify all subjects undergoing nephrectomy in Alberta, Canada, from 2002 to 2007 using administrative codes. Comorbid conditions were determined using validated algorithms, and baseline estimated glomerular filtration rate (eGFR) and proteinuria status were determined.

Measurements: Postsurgical outcomes of end-stage renal disease, acute dialysis, chronic kidney disease (CKD) (eGFR < 30 mL/min per 1.73 m²), and rapidly progressive CKD (eGFR < 60 mL/min per 1.73 m² and eGFR loss ≥ 4 mL/min per 1.73 m² per year) were assessed. The risk and risk factors for developing the composite renal outcome were determined using a multivariable Cox proportional hazards model. **Results and Limitations:** Of 1151 subjects, 10.5% developed an adverse renal outcome over a mean of 32 mo. Complete (vs. partial) nephrectomy was associated with a hazard ratio (HR) of 1.75 (95% confidence interval [CI], 1.02-2.99) for the primary outcome, as was lower baseline eGFR. Subjects with proteinuria were more likely to experience the primary outcome (42% vs. 9%), conferring an adjusted HR of 2.40 (95% CI, 1.47-3.88).

Conclusions: Clinically important adverse renal outcomes are common in patients undergoing nephrectomy for renal tumors. In addition to baseline eGFR and the extent of the renal mass removed, proteinuria is a strong independent risk factor. Assessment of proteinuria, in addition to other risk factors, should be performed to inform prognosis and the optimal treatment strategy.

Editorial Comment

The authors analyzed 1151 patient who underwent complete or partial nephrectomy. Surprisingly, they found that a significant proportion of subjects (10.5%) developed clinically relevant adverse renal outcomes within 2.7 years after nephrectomy. The most relevant information within this report is that in addition to the expected association of decreased baseline renal function, proteinuria at baseline was a strong independent risk factor, conferring more than a two-fold risk.

A good and simple clinical advise therefore is to check for proteinuria before the operation and if proven, to regard this as a significant prognostic factor for adverse renal outcome. Partial nephrectomy or nephron-sparing surgery should be strongly considered in these cases.

Dr. Andreas Bohle*Professor of Urology**HELIOS Agnes Karll Hospital**Bad Schwartau, Germany**E-mail: boehle@urologie-bad-schwartau.de*

NEUROLOGY & FEMALE UROLOGY

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Tape Fixation: An Important Surgical Step to Improve Success Rate of Anti-Incontinence Surgery

Rechberger T, Futyma K, Jankiewicz K, Adamiak A, Bogusiewicz M, Bartuzi A, Miotła P, Skorupski P, Tomaszewski J

Second Department of Gynecology, Medical University of Lublin, Lublin, Poland

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Purpose: Mid urethral slings are effective surgical treatment for stress urinary incontinence. However, 5% to 20% of patients still experience surgical failure with clinically significant recurrent or persistent stress urinary incontinence. Since a subset of these failures may be caused by improper tape position, we elucidated whether additional paraurethral fixation of a tape to prevent displacement during tensioning could improve the transobturator sling outcome.

Materials and Methods: The study was done in 463 patients with stress urinary incontinence who were randomly allocated to treatment with a standard transobturator intravaginal monofilament sling procedure (232) or to an intravaginal transobturator monofilament sling with additional 2-point tape fixation (231). Another 2 absorbable sutures parallel to the urethra were added to fix the tape and prevent displacement during tape tensioning. Outcome was assessed by a cough test and a 1-hour pad test at 12 months.

Results: Clinical efficacy of the procedure with fixation was significantly higher with 195 women (95.12%) cured or improved compared to the 199 (88.73%) cured or improved with the standard sling (chi-square 5.71, $p = 0.0169$). There was no increase in intraoperative or postoperative complications. Also, among patients with intrinsic sphincter deficiency we noted a significantly better outcome in the fixation group than in the control group, that is 39 of 41 patients (95.1%) cured or improved vs. 31 of 42 (73.8%) (chi-square 10.65, $p = 0.0011$).

Conclusions: Tape fixation significantly increases the clinical efficacy of the transobturator sling, especially in patients with intrinsic sphincter deficiency.

Editorial Comment

In this well designed work by Rechberger and cols. mid urethral slings are compared regarding their efficacy when coupled with a simple addition in the surgical technique: a pair of Vycril stitches alongside the urethra to assure better tape fixation and prevent displacement. Not only this simple technique improved results objectively and subjectively, but it also provided better clinical outcome in patients with ISD, which are known to be harder to treat. Some urogynecologists already perform this maneuver intuitively but this paper adds strong evidence that this is a valid intraoperative detail that may reflect in treatment results improvement.

Dr. Ricardo Miyaoka
State University Campinas
Campinas, SP, Brazil
E-mail: rmiyaoka@uol.com.br

Bladder augmentation and urinary diversion in patients with neurogenic bladder: Non-surgical considerations

Stein R, Schröder A, Thüroff JW

Division of Pediatric Urology, Department of Urology, University Medical Center, Johannes Gutenberg University, Mainz, Langenbeckstrasse 1, 55131 Mainz, Germany

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Segments from almost all parts of the bowel have been used for urinary diversion. As a result, the available absorptive surface area of the bowel is reduced, and the incorporation of bowel segments into the urinary tract may have metabolic consequences. This is an area somewhat neglected in the literature. Metabolic complications are rare, but sub-clinical metabolic disturbances are quite common. Several studies have demonstrated that some of the absorbent and secreting properties of the bowel tissue are preserved after incorporation into the urinary tract. Hyperchloraemic metabolic acidosis can occur if ileal and/or colon segments are used, as well as malabsorption of vitamin B(12) and bile acid after the use of ileal segments. These metabolic effects are not as severe as may be suspected and can be prevented by prophylactic substitution. Secondary malignancies can develop as a long-term consequence of bladder augmentation. Using colonic segments, tumours are most likely to occur at the ureteral implantation site. To prevent metabolic complications, careful patient selection and meticulous and lifelong follow-up, as well as prophylactic treatment, are mandatory. Endoscopy for early detection has been recommended, starting 10 years postoperatively for patients who underwent surgery for a benign condition.

Editorial Comment

This is a nice review on the topic of non surgical complications implicated in bladder augmentation and urinary diversion in pediatric neurogenic bladder patients. Although the article does not bring any outrageously new fact out it does remind us of the severe implications that may take place following this type of surgery, notably in children. There should be a concern regarding this specific population as less invasive treatments lack efficacy and must be repeated continuously and regularly for a lifelong period.

Although the use of intestinal segments have been widely used for many years it seems clear that it is far from being the ideal solution. Research in tissue engineering may bring a more suitable alternative in the future.

Dr. Ricardo Miyaoka*State University Campinas**Campinas, SP, Brazil**E-mail: rmiyaoka@uol.com.br*

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GERIATRIC UROLOGY

The importance of pelvic lymph node dissection in the elderly population: implications for interpreting the 2010 national comprehensive cancer network practice guidelines for bladder cancer treatment

Abdollah F, Sun M, Shariat SF, Schmitges J, Djahangirian O, Tian Z, Jeldres C, Perrotte P, Montorsi F, Karakiewicz PI

Cancer Prognostics and Health Outcomes Unit, Montreal, Quebec, Canada; Department of Urology, Vita Salute San Raffaele University, Milan, Italy

J Urol. 2011; 185: 2078-84

Purpose: National Comprehensive Cancer Network practice guidelines indicate that pelvic lymph node dissection can be omitted at radical cystectomy in elderly patients. We examined the pelvic lymph node dissection rate in patients 80 years old or older and the impact of pelvic lymph node dissection on cancer specific and overall mortality in these patients.

Materials and Methods: We examined the records of 11,183 patients treated with radical cystectomy in 17 Surveillance, Epidemiology and End Results registries. We performed univariate and multivariate Cox regression analysis to test the effect of pelvic lymph node dissection on cancer specific and overall mortality. **Results:** Overall pelvic lymph node dissection was omitted in 25% of patients, including 24.2% younger than 80 years and 30.8% 80 years old or older ($p < 0.001$). The 5-year rate of freedom from cancer specific mortality for pelvic lymph node dissection vs no pelvic lymph node dissection was 62.5% vs 59.9% in patients younger than 80 years, and 50.0% vs 46.1% in those 80 years old or older ($p = 0.01$ and 0.005 , respectively). The 5-year rate of freedom from overall mortality for the same categories was 48.8% vs 43.9% and 28.3% vs 24.7% ($p < 0.001$ and 0.01 , respectively). On multivariate analysis omitting pelvic lymph node dissection was associated with a 1.3-fold higher cancer specific rate at ages less than 80 and 80 years or greater (each $p < 0.001$). Omitting pelvic lymph node dissection was also associated with a 1.3-fold higher overall mortality rate, including 1.3 at ages less than 80 years and 1.2-fold at ages 80 years or greater (each $p \leq 0.005$).

Conclusions: Results indicate that pelvic lymph node dissection was more often omitted in patients 80 years old or older than in those younger than 80 years. However, the protective effect of pelvic lymph node dissection on cancer specific and overall mortality was virtually the same in the 2 age categories. Thus, advanced age should not be a limiting factor for performing pelvic lymph node dissection at radical cystectomy.

Editorial Comment

Unfortunately, evidence-based practice guidelines regarding the oncological management of elderly patients are sparse. In this scenario, authors are commended for highlighting that elderly patients might be denied the opportunity to receive the most effective treatment for their disease on the basis of chronological age alone.

Based on Surveillance, Epidemiology and End Results (SEER) database, pelvic lymph node dissection (PLND) was more often omitted in elderly patients (> 80 years) and when performed, tended to be less extensive (< 10 lymph nodes). However, metastasis rate was similar in patients younger than 80 and 80 years old or older (26.1% vs 25.1%) and patients with a lymph node count of 10 or greater had significantly more favorable cancer specific and overall mortality rates than their counterparts with < 10 lymph nodes. These results remained constant when patients were stratified by age less than 80 vs 80 years or greater.

Interestingly, PLND omission was less common in more contemporary study years, that is 38.6% between 1988 and 1992 vs 17.5% between 2003 and 2006 ($p < 0.001$).

Although virtually all patients treated with radical cystectomy are judged to be fit candidates for such a major surgical procedure, future studies should consider comorbidities and the perspective of quality-of-life adjusted relative to survival benefits in a prospective design to confirm presented results, to provide better understanding of the effect of age on tumor biology and patient survival and to improve cancer care in the elderly.

Dr. Leonardo Oliveira Reis
Assistant Professor of Urology
University of Campinas, Unicamp
Campinas, São Paulo, Brazil
E-mail: reisleo@unicamp.br

The illusion of prostate-specific antigen decline in patients with metabolic syndrome and insulin resistance

Choi HC, Park JH, Cho BL, Son KY, Yoo YJ, Kwon HT

Department of Family Medicine, Seoul National University Hospital, Department of Family Medicine, Health-care System Gangnam Centre of Seoul National University Hospital, Seoul, South Korea

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Study Type - Symptom prevalence (prospective cohort) Level of Evidence 1b What's known on the subject? and What does the study add? Studies have shown that PSA is negatively associated with obesity as a result of hemodilution or metabolic effect. Hemodilution could be the main reason for low PSA levels in obese men. However, the intrinsic metabolic effects such as insulin resistance (IR) or metabolic syndrome (MS) on PSA level have not been clearly evaluated although obesity is closely tied to MS and IR. We regarded MS and IR as the pathophysiological cornerstone of metabolic disorder in obesity and analyzed the relationships among MS, IR, and PSA levels, and plasma volume by using the concept of PSA mass, the total circulating PSA protein. PSA mass did not change depending on the severity of the obesity, MS or IR. Even the group with both MS and IR, which could be the most metabolically disturbed in this study, did not have different PSA mass, comparing with the group without any MS or IR. Thus, the decline in PSA level in men with MS or IR can be also explained by increased plasma volume other than any intrinsic metabolic effects.

Objective: To investigate the detailed mechanism of prostate-specific antigen (PSA) decline in metabolic syndrome (MS) and insulin resistance (IR), which lowers the predictive value of the PSA test, we examined the effect of haemodilution and the possibility of an intrinsic metabolic effect.

Patients and Methods: We analysed 28,315 men who underwent routine check-ups. We compared the age-adjusted mean PSA levels in subjects with and without MS before and after adjusting or stratifying the plasma volume. We analysed changes in PSA level, plasma volume and PSA mass according to obesity grade, number of MS components, IR severity and diagnosis of MS, IR or both using an analysis of covariance.

Results: The PSA levels were lower in the group with MS than in the group without MS ($P = 0.001$), but this difference disappeared after adjusting or stratifying the plasma volume ($P > 0.05$ for all). The PSA levels decreased, plasma volume increased, and PSA mass did not change as the number of MS components increased ($P = 0.002$, $P < 0.001$, $P = 0.55$, respectively) or the IR severity increased ($P = 0.001$, $P < 0.001$, $P = 0.34$, respectively). Similarly, PSA levels were lower, plasma volumes were higher and PSA masses were the same in subjects with MS ($P = 0.002$, $P < 0.001$, $P = 0.10$, respectively), IR ($P = 0.018$, $P < 0.001$, $P = 0.94$, respectively), or both ($P = 0.003$, $P < 0.001$, $P = 0.86$, respectively) than in subjects without those conditions.

Conclusion: The PSA decline in MS and IR may result simply from a haemodilution effect and be unrelated to intrinsic metabolic disturbances. For this reason, PSA levels could be underestimated in patients with MS or IR because of haemodilution.

Editorial Comment

Prostate-specific antigen (PSA) is the most widely used marker for prostate cancer screening. However, the presence of other benign processes and a myriad of situations may confound the interpretation of PSA levels.

Authors present an elegant cross-sectional study regarding conditions that could affect the validity of PSA tests in prostate cancer screening and showed no difference in PSA levels between subjects with and without metabolic syndrome after adjusting for the plasma volume.

The decrease in PSA levels observed in patients with metabolic syndrome (MS) or insulin resistance (IR) could simply be the result of a haemodilution effect and not related to intrinsic metabolic disturbances.

Thus, when interpreting PSA levels in men with MS or IR, we should consider that the PSA level could be underestimated because of haemodilution.

Although the utilization of the concept of PSA mass is a virtue, most of study limitations were recognized by authors and further analyses considering direct measurement of plasma volume using an isotope, prostate volume and visceral adipose tissue together are necessary to define the relationships and the use of such calculations for PSA evaluation must also be validated.

On top of that, these patients are commonly exposed to drugs such as nonsteroidal anti-inflammatory (NSAID; $P = 0.03$), statin ($P = 0.01$), and thiazide diuretic ($P = 0.025$) that intake was recently inversely related to PSA levels (1). In this setting, adjusting for potential confounders including demographics, clinical characteristics, physical examination, laboratory studies, and duration of medication use are warranted once five years of NSAID, statin, and thiazide diuretic use was associated with PSA levels lower by 6%, 13%, and 26%, respectively. The combination of statins and thiazide diuretics showed the greatest reduction in PSA levels: 36% after 5 years. On the other hand, concurrent calcium channel blocker use minimizes or negates the inverse relationship of statin use and PSA level.

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Dr. Leonardo Oliveira Reis
Assistant Professor of Urology
University of Campinas, Unicamp
Campinas, São Paulo, Brazil
E-mail: reisleo@unicamp.br

PEDIATRIC UROLOGY

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Instituting a conservative management protocol for pediatric blunt renal trauma: evaluation of a prospectively maintained patient registry

Fitzgerald CL, Tran P, Burnell J, Broghammer JA, Santucci R

Detroit Medical Center, Detroit, Michigan, USA

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Purpose: Retrospective studies show that even high grade pediatric renal trauma can be safely managed conservatively. We evaluated a prospective patient registry at our level 1 pediatric trauma center, where patients with renal trauma were treated with an institutional review board approved conservative blunt renal trauma protocol. Standardized treatment included a trial of expectant management for all stable cases.

Materials and Methods: We identified 39 children with blunt renal trauma treated between 2003 and 2008. A strict conservative approach was used, ie nonoperative management in cases that were hemodynamically stable or had a favorable response with up to 2 units of blood transfused and no operative renal lesion on imaging. Adult imaging protocols were followed and exploratory laparotomy for nonrenal causes did not alter course of expectant renal management. Outcomes evaluated were injury grade, hematuria, operative management, length of stay and associated injuries.

Results: Based on the American Association for the Surgery of Trauma organ injury severity scale, 13 patients were considered to have grade I disease, 8 grade II, 11 grade III, 6 grade IV and 1 grade V. Conserva-

tive management resulted in a 97% nonoperative rate and a single renorrhaphy.

Conclusions: Using a prospective patient registry, this study demonstrates that conservative treatment of blunt pediatric renal trauma is safe and effective. Also, serious renal injuries are not missed by applying adult diagnostic imaging protocols in children.

Editorial Comment

These authors instituted a conservative management protocol for blunt renal trauma in pediatric patients that mirrored their adult protocol. This study reports on their five-year experience using the new protocol at their institution. They also used adult imaging guidelines to diagnose and categorize renal injuries. They had 39 patients with confirmed blunt renal trauma during this time frame and all but one was able to be managed conservatively. As expected, most of the injuries were lower grade injuries but they did have six Grade IV injuries and one Grade V injury. Endoscopic management or percutaneous drainage was still categorized as being conservative. When this new prospective data is combined with their prior retrospective experience, nearly 80% of pediatric patients with high-grade blunt renal trauma were able to be managed expectantly. This study helps provide further evidence that the adult approach of non-operative management for high-grade blunt renal trauma can be applied safely in hemodynamically stable children; however, long-term functional outcome data is still needed.

Dr. M. Chad Wallis

Division of Pediatric Urology

University of Utah

Salt Lake City, Utah, USA

E-mail: chad.wallis@hsc.utah.edu

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Tonsillectomy does not improve bedwetting: results of a prospective controlled trial

Kalorin CM, Mouzakes J, Gavin JP, Davis TD, Feustel P, Kogan BA

Department of Urology, Albany Medical Center, Albany, New York, USA

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Purpose: Sleep disordered breathing caused by tonsillar hypertrophy has been implicated as a cause of primary and secondary nocturnal enuresis in children. We prospectively studied the preoperative and postoperative rates of nocturnal and daytime incontinence in a group of children with tonsillar hypertrophy undergoing tonsillectomy compared to a matched control group undergoing surgery unrelated to the airway or urinary tract.

Materials and Methods: A total of 326 toilet trained children 3 to 15 years old were included, with 257 in the tonsillectomy group and 69 in the control group. Severity of tonsillar hypertrophy was graded preoperatively on a scale of 1 to 4. A voiding questionnaire regarding number of bedwetting and daytime incontinence episodes per week, voids per day, bowel movements per week, secondary or primary enuresis and family history was completed by parents preoperatively, and at 3 and 6 months postoperatively.

Results: Preoperatively the respective rates of nocturnal enuresis and daytime incontinence were 33% and 17% in the tonsillectomy group ($p = 0.89$), and 35% and 14% in the control group ($p = 0.3$). The respective cure rates for bedwetting at 3 and 6 months postoperatively were 40% and 50% in the tonsillectomy group ($p = 0.60$), and 35% and 48% in the control group ($p = 0.61$). Similarly no difference was seen in improvement or cure of daytime incontinence at 3 and 6 months postoperatively.

Conclusions: We found no association between tonsillar hypertrophy and urinary incontinence before or after tonsillectomy.

Editorial Comment

There have been a number of reports in the literature suggesting that tonsillectomy may be beneficial for the treatment of nocturnal enuresis. Because the current literature contains largely retrospective reviews and case reports, the authors sought to design a prospective controlled trial to determine whether tonsillectomy would improve daytime or nighttime incontinence postoperatively. They had 257 patients in the tonsillectomy group that all had evidence of tonsillar hypertrophy and 69 patients in the control group who were scheduled to undergo minor outpatient surgery for unrelated problems. They found similar rates of daytime and nighttime incontinence in both groups. They performed follow-up visits at three and six months and found improvement in both the study and control groups. There was no statistically significant difference between the two groups in terms of resolution or improvement of their incontinence either during the daytime or at night.

This was a nice prospective controlled study that should give one pause before suggesting to patients or parents that bedwetting is an indication for tonsillectomy. While there still remains an association between disordered breathing during sleep, upper airway obstruction, and enuresis, it is not clear yet how to tease out which patients would benefit from removal of their tonsils and/or adenoids versus the more proven methods of medical and behavioral management.

Dr. M. Chad Wallis
Division of Pediatric Urology
University of Utah
Salt Lake City, Utah, USA
E-mail: chad.wallis@hsc.utah.edu