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PRINCIPAL INVESTIGATOR: Dr. Theresa Koppie

CONTRACTING ORGANIZATION: University of California, Davis Davis, CA 95618

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INTRODUCTION:

Patients with early stage prostate cancer have excellent cause specific survival after definitive local therapy with radiation therapy or radical prostatectomy. However, regardless of race, men of lower socioeconomic status are less likely to receive definitive local therapy for early stage disease, and when such treatment is administered, they are more likely to die of their cancer. Men of lower socioeconomic status are also more likely to have treatment related complications after prostate cancer treatment. This suggests that disparities in treatment, rather than prostate cancer screening, may play a causative role in observed differences. We hypothesize that socioeconomic disparities in prostate cancer survival are associated with distinct differences in quality of care that can be identified and measured using standard medical diagnosis and treatment codes. Therefore, our aims are 1. To identify socioeconomic disparities in quality of care for localized prostate cancer and 3. To develop a tool to measure disparities in quality of care for localized prostate cancer.

BODY:

In this section of the report, I am to describe the research accomplishments associated with each task outlined in the approved Statement of Work. I have copied my approved statement of work below. As planned, I have completed phase I and most of phase II of the project, which includes data organization and cleaning. I have changed institutions to Oregon Health Sciences University at month 20, and have submitted a new statement of work, which I am including below.

STATEMENT OF WORK

Phase I: Institutional and SEER clearance.

Months 0-6

Outcome: Approval for the study. Obtain data for the study.

Task 1. Obtain Institutional Review Board (IRB) Approvals (Months 0-6). Task 2. Obtain data from SEER Medicare databases. Submit 10 page online proposal to the SEER Medicare program. The approval process takes approximately 6 weeks. Once approved, we can then purchase SEER Medicare linked data.

Phase II: Data organization and cleaning.

Months 6-20

Outcome: Data suitable for statistical analysis

Task 1. Programming to develop variables of interest from billing codes.

Task 2. Evaluate variables of interest. Check for internal consistency. Exclude invalid fields where appropriate.

***Transition from UC Davis to OHSU

Months 20-24

Outcomes: Successful move of data from UCD to OHSU

Task 1: Notify biostats and programming support at UCD of plans to move. Notify UCD IRB of plans to close study. Notify the SEER registry of plans to move data. Task 2: Re apply for SEER data: The SEER registry strictly enforces their data protection protocol, thus no SEER data is to move from institution to institution. Programming codes can move institutions, however. A completely new application will be submitted. I anticipate this will take 4 months. Previous programming code can then be applied.

Phase III: Data analysis and presentation Months 24-40 Outcome: Results suitable for publication/presentation.

Task 1. The association between socioeconomic status and disease specific outcome measures will be evaluated using Cox proportional hazard models and Kaplan Meier analyses for overall and disease specific survival. A multivariate regression analysis will be performed controlling for age and comorbidity.

Task 2. To evaluate the association between socioeconomic status and treatment specific outcome measures using logistic regression analysis.

As stated in Phase I, we have obtained IRB approvals as well as access to the SEER Medicare linked dataset. The IRB approval process took approximately 3 months. We sought access to SEER Medicare linked data concurrently. This took over 6 months to achieve due to staffing shortages at the NCI, and we have recently received the data. During this interval we also sought appropriate statistical support. With the help of grant funds, we are providing partial salary support to a recent PhD from our department of biostatistics and epidemiology, Clayton Schupp. On a personal note, I was on maternity leave from May to September, and had sought DOD approval for leave during this period.

As for Phase II of our statement of work, our first look at the dataset demonstrated that there would be a significant amount of work required to evaluate and clean the dataset for analysis. There are many cases for which variables were unknown that needed to be explored within the SEER dataset. In addition, significant programming was required to score comorbidities, evaluate socioeconomic status from census and zip code data, and organize PSA (prostate specific antigen) data for potential use. Much of this work has been done with Yolanda Hagar in the department of statistics at UC Davis, as Clayton Schupp took a position in the San Francisco Bay Area.

From the SEER dataset, we were able to identify our study cohort. (Table 1) Our population consisted of 177,668 men with localized prostate cancer over 65. Most men were in the 65-69 year old range (40%), and there were fewer men over 80 within the cohort (9%). The majority of patients were Caucasian (80%). The majority of patients were married (75%). Most patients (60%) had grade 6 and 7 disease.

Evaluation of the socioeconomic variables demonstrated that regardless of how we defined SES, there was a significant impact of SES on survival after prostate cancer treatment (Figures 1 and 2). We have decided to define SES by both income and education, by defining a variable which is a summary of both zip code level median income and proportion completing high school.

We then began the process of linking to the Medicare dataset, where billable clinical activities around the time of diagnosis and treatment could be assessed. Using billing codes and coding tables that we have defined previously (Appendix ii, Appendix iii), we began our analysis. The first outcome measure we will investigate will be urinary side effects of prostate cancer treatment. Because urinary continence and urinary side effects are exquisitely sensitive to subtle differences in treatment technique (radiation, surgery), we believe it was an ideal starting point. Our initial findings have been quite striking. Most patients who undergo treatment (78%) (Table 2). Furthermore, there appears to be an association between the frequency of urinary incontinence and socioeconomic status as defined by education (Table 3) and by median income (Table 4).

KEY RESEARCH ACCOMPLISHMENTS:

• Hellenthal NJ, Parikh-Patel A, Bauer K, Ralph W, deVere W, Koppie TM. Men of higher socioeconomic status have improved outcomes after radical prostatectomy for localized prostate cancer. Urology. 2010 Dec; 76(6):1409-13. PubMed PMID: 20888034

REPORTABLE OUTCOMES:

- We have completed and submitted a manuscript for publication in the journal, Urology. This manuscript has been accepted for publication in upcoming months: "Men of higher socioeconomic status have improved outcomes after radical prostatectomy for localized prostate cancer" Nicholas J. Hellenthal¹, Arti Parikh-Patel², Katrina Bauer², Ralph W. deVere White¹, Theresa M. Koppie¹
- 2. We have developed a SEER medicare linked database for men of medicare age who are diagnosed with prostate cancer. This database includes patient demographics, cancer staging, cancer treatment information, cancer specific survival, as well as all medicare billing during the course of their treatment.
- 3. An abstract has been submitted to the 2011 IMPACT meeting: PC081735, Developing an Instrument to Measure Socioeconomic Disparities in Quality of Care for Men with Early-Stage Prostate Cancer
- 4. Collaboration with Sergio Aguilar-Gaxiola, Director of the Center to Reduce Health Disparities at UC Davis School of Medicine on psychosocial disparities for men with erectile dysfunction after prostate cancer treatment.
- 5. Collaboration with Moon Chen, PhD, MPH, Associate Director for Disparities and Research at UC Davis relating to prostate cancer in Asian American men.
- 6. Development of a Health Disparities Conference, scheduled for February 2011, where Carmen Moten, Program Director/Health Scientist Administrator in the Disparities Training Branch, Center to Reduce Cancer Health Disparities (CRCHD) of the National Cancer Institute (NCI) will guest lecture on health disparities.
- 7. Collaboration with Jennifer Anger MD, MPH at Cedars Sinai/UCLA to explore interaction between socioeconomic status and post treatment urinary side effects. Currently, our analyses are moving towards our first publication.

CONCLUSION: To date, we have obtained our data and invested significant time in data cleaning and programming. We have had several publishable findings regarding the impact of SES on our initial endpoint, urinary incontinence, and are moving towards publication in this area.

REFERENCES:

Hellenthal NJ, Parikh-Patel A, Bauer K, Ralph W, deVere W, Koppie TM. Men of higher socioeconomic status have improved outcomes after radical prostatectomy for localized prostate cancer. Urology. 2010 Dec; 76(6):1409-13. PubMed PMID: 20888034

APPENDICES:

Appendix i. ICD-9, CPT-4, and HCPCS Codes to assess outcome after prostate cancer treatment.

Appendix ii. ICD-9, CPT-4, and HCPCS Codes to quality of care for prostate cancer.

PERSONNEL:

Theresa Koppie, MD – Principal Investigator Clayton Schupp, PhD – Graduate Student Researcher advanced to Postdoctoral Scholar

SUPPORTING DATA:

Table 1. Clinical characteristics of patients with prostate cancer identified from the SEER dataset.

Clinical Ch	n	
Age	65-69	52456
	70-74	50680
	75-79	40214
	80-84	22039
	85+	12279
Race	White	142814
	Black	19251
	Asian	6137
	Hispanic	4482
	Native American	374
	Other	4610
Marital Status	Single	12145
	Married	120442
	Separated	1014
	Divorced	8460
	Widowed	16162
	Unknown	19445
Grade	1	4809
	2	106243
	3	54591
	4	575
	Unknown	11450
Stage	T1	1300
	T2	10929
	Т3	5004
	T4	9097
	Unknown	151338

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Figure 1. Prostate cancer survival as stratified by SES, when SES is defined by median income.



Figure 2. Prostate cancer survival as stratified by SES, when SES is defined by level of education.

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Stratified by Income Level

Table 2	Frequency	of incontinence amo	na natients treated	for prostate cancer.
	riequency	or incontinence arrio	ny patients treated	i fui prostate cancer.

	Diagnosis	Number	Percent
599.82	Intrinsic Sphincter Deficiency	1617	1.58
788.30	Incontinence of urine	21878	21.33
788.31	Urge incontinence	20354	19.84
788.32	Stress incontinence, male	27928	27.23
788.33	Mixed incontinence, male or female	6489	6.33
788.34	Incontinence w/o sensory awareness	1177	1.15
Missing/No	ne	23127	22.55

Table 3. Frequency of urinary incontinence according to SES as defined by completion of high school.

•	Finish HS				
	<= 1st Q	1st Q < inc <= median	median < inc <= 3rd Q	3rd Q < inc	Total
Intrinsic Sphincter	516	191	342	568	1617
Deficiency	0.32	0.12	0.21	0.35	1.01
Incontinence of urine	6060	5636	5208	4974	21878
Incontinence of urme	3.77	3.51	3.24	3.10	13.61
Urgo incontinonco	5708	5129	4640	4877	20354
Urge incontinence	3.55	3.19	2.89	3.03	12.67
	8384	8128	5365	6051	27928
Stress incontinence, male	5.22	5.06	3.34	3.77	17.38
Mixed incontinence, male	1935	1558	1378	1618	6489
or female	1.20	0.97	0.86	1.01	4.04
Incontinence w/o sensory	543	351	149	134	1177
awareness	0.34	0.22	0.09	0.08	0.73
Nono	21962	20914	19309	19072	81257
None	13.67	13.01	12.02	11.87	50.56
Total	45108	41907	36391	37294	160700
Total	28.07	26.08	22.65	23.21	100.00

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	Median Income				
	<= 1st Q	1st Q < inc <= median	median < inc <= 3rd Q	3rd Q < inc	Total
Intrinsic Sphincter	364	451	375	427	1617
Deficiency	0.46	0.57	0.47	0.54	2.04
Incontinence of urine	5914	4913	5160	5891	21878
Incontinence of urme	7.44	6.18	6.50	7.42	27.54
Urgo incontinonoo	4810	4746	5550	5248	20354
Urge incontinence	6.05	5.97	6.99	6.61	25.62
Change in continuous male	7975	6752	6592	6609	27928
Stress incontinence, male	10.04	8.50	8.30	8.32	35.15
Mixed incontinence, male	1640	1589	1657	1603	6489
or female	2.06	2.00	2.09	2.02	8.17
Incontinence w/o sensory	116	256	346	459	1177
awareness	0.15	0.32	0.44	0.58	1.48
None	19153	19824	20620	21660	81257
None	24.11	24.95	25.96	27.26	102.28
Tatal	39972	38531	40300	41897	160700
Total	24.87	23.98	25.08	26.07	100.00

Appendix i. ICD-9, CPT-4, and HCPCS Codes to assess outcome after prostate cancer treatment.

Radical prostatectomy: CPT: 55840 (Retropubic radical prostatectomy), 55842 (Prostatectomy, retropubic radical, with or without nerve sparing; with lymph node biopsy(s), 55845 (Retropubic radical prostatectomy with bilateral pelvic lymph node dissection), 55810 (Perineal radical prostatectomy), 55815 (Perineal radical prostatectomy with bilateral pelvic lymph node dissection), and 55866 (Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing).

Diagnosis of Surgical Complications:

ICD-9: 599.1 (Urethral fistula), 596.1 (Intestinovesical Fistula), 596.2 (Vesical Fistula Nec), 596.6 (Bladder Rupt (Non Traumatic), 565.1 (Anal Fistula), 569.3 (Rectal Anal Hemorrhage), 569.83 (Perforation Of Intestine), 569.4 (Anal or Rectal Ulcer/Pain/Tear-Old/Disease), 998.1 (Hemorrhage or Hematoma complicating a procedure), 998.83 (Non-Healing Surgical Wound), 998.9 (Surgical Complication NOS), 998.2 (accidental puncture or laceration during a procedure), 998.3 (disruption of operative wound), 998.4 (Foreign Body left during procedure), 998.5 (Infected Post-Op Seroma/Other Infection), 998.6 (Persist Post-Op Fistula), 998.7 (Post-Op Foreign Substance Reaction), 604.0 (Orchitis with Abscess), E870.0 (Acc Cut/Hem in Surgery), E870.4 (Acc Cut/Hem with Scope Exam), E870.7 (Acc Cut/Hem with Enema), E870.8 (Accidental Cut in Med Care Nec), E870.9 (Accidental Cut in Med Care Nos), E871.0 (Post-Surgical Foreign Body), E873.0 (Excess Fluid in Infusion), E876.0 (Mismatch Blood-Transfusion), 956.0 (Injury to Sciatic Nerve), 956.1 (Injury to Femoral Nerve), 956.4 (Injury to cutaneous sensory nerve lower limb), 956.5 (Injury to nerve Pelvic/Leg), 956.8 (Injury to Multiple Nerves of Pelvic and Leg), 956.9 (Injury to Nerves in Pelvic/Leg Nos), 902.50 (Injury to Iliac Vessel Nos), 902.51 (Injury to Hypogastric Artery), 902.52 (Injury to Hypgastric Vein), 902.53 (Injury to Iliac Artery), 902.54 (Injury to Iliac Vein), 902.59 (Injury to Iliac Vessel Nec), 590.10 (Acute pyelonephritis without lesion of renal medullary necrosis), 590.80 (Pyelonephritis Nos), 590.9 (Kidney infection), 595 (Acute Cystitis), 595.0 (Acute Cystitis), 595.3 (Trigontitis), 595.89 (Cystitis Nec), 595.9 (Cystitis Nos), 599 (Urinary tract infection, site not specified), 599.0 (Urinary Tract Infection Nos), 599.00 (Urinary Tract Infection Nos), 599.1 (Uretheral Fistula), 599.2 (Uretheral Diverticulum), 599.7 (Hematuria), 996.31 (Malfunction of Uretheral Catheter), 996.64 (React-Indwell Urine Catheter), 996.65 (complication or infection due to urethral catheter), 998.5 (postoperative infection)

Diagnosis of GU Surgical Complications: 595.89 (Cystitis Nec), 590.1 (Acute Pyelonephritis), 590.2 (Renal/Perirenal Abscess), 590.8 (Pyelonephritis or pyonephrosis not specified as acute or chronic), 590.9 (Injection Of Kidney Nos), 591 (Hydronephrosis), 997.5 (Surgical Compl-Urinary Tract), 596.1 (Intestinovesical Fistula), 596.2 (Urethrovesical fistula), 596.6 6 (Rupture of bladder, nontraumatic), 593.3 (Stricture of kinking of ureter (postoperative), 593.4 (Ureteric Obstruction Nec), 593.5 (Hydroureter), 593.81 (Renal Vascular Disorder), 593.82 (Ureteral Fistula), 457.8 (NonInfection Lymph Disease), 567.2 (Peritonitis), 567.8 (Choleperitonitis/Sclerosing Mesenteritis/Peritonitis), 595.89 (Cystitis), 682.2 (Cellulitis of Trunk), 998.59 (Other Post-Op Infection)

Treatment of Urological Complications

CPT code: 36430 (Blood transfusion), 49000 (Exploratory laparotomy), 50392 (Percutaneous nephrostomy tube placement), 50780 (Ureteroneocystostomy), 51800 (Revision of bladder/urethra), 51860 (Cystorrhaphy, suture of bladder wound), 52332 (Insertion of ureteral stent)

Diagnosis of urinary incontinence: ICD-9: 599.82 (Intrinsic sphincter deficiency), 788.30 (incontinence of urine), 788.31 (urge incontinence),788.32 (stress incontinence, male), 788.33 (Mixed incontinence, male, female), and 788.34 (incontinence without sensory awareness).

Treatment of urinary incontinence: CPT codes: 51715 (Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck), 95028 (Intracutaneous (intradermal) tests

with allergenic extracts, delayed type reaction, including reading), 53440 (Sling operation for correction of male urinary incontinence, fascia or synthetic), 57288 (Sling operation for stress incontinence, fascia or synthetic), 51992 (Laparoscopy, surgical; sling operation for stress incontinence, fascia or synthetic) 53442 (remove or revise male sling), 53444 (Insertion of tandem cuff (dual cuff)), 53445 (Insertion of inflatable urethral/bladder neck sphincter, including placement of pump, reservoir & cuff), 53446 (Removal of inflatable urethral/bladder neck sphincter, including pump, reservoir & cuff), 53447 (Removal & replacement of inflatable urethral/bladder neck sphincter, including pump, reservoir & cuff at same operative session), 53448 (Removal & replacement of inflatable urethral/bladder neck sphincter including pump, reservoir & cuff through an infected field at same operative session including irrigation and debridement of infected tissue), and 53449 (Repair of inflatable urethral/bladder neck sphincter, including pump, reservoir & cuff).

Diagnosis of Outlet Obstruction

ICD-9 diagnosis: 596.0, 596.00 (bladder neck obstruction), 599.6 (urinary obstruction), 788.2 (retention of urine), 788.21 (incomplete bladder emptying), 788.29 (other specified retention of urine), 788.38 (overflow incontinence), 788.62 (slowing of urinary stream)

Management of Outlet Obstruction

CPT code: 51701 (urethral/bladder catheterization (simple); 51010, 51040 (cystostomy), 52640, (transurethral resection of postoperative bladder neck contracture), 52276 (visual, optical internal urethrostomy), 52281 (Cystourethroscopy, with calibration and/or dilation of urethral stricture or stenosis, with or without meatotomy, with or without injection procedure for cystography, male or female), 52282 (Cystourethroscopy, with insertion of urethral stent), 52283 (Cystourethroscopy, with steroid injection into stricture), 52450 (Transurethral incision of prostate), 52500 (Transurethral resection of bladder neck (separate procedure), 52510 (Transurethral balloon dilation of the prostatic urethra, any method), 52640 (Transurethral resection; of postoperative bladder neck contracture), 53600 (Dilation of urethral stricture by passage of sound or urethral dilator, male; initial), 53601 (Dilation of urethral stricture by passage of sound or urethral dilator, male; subsequent), 53605 (Dilation of urethral stricture or vesical neck by passage of sound or urethral dilator, male, general or conduction (spinal) anesthesia), 53620 (Dilation of urethral stricture by passage of filiform and follower, male; initial), 53621 (Dilation of urethra). ICD-9: 57.92 (Dilation of bladder neck), 58.0 (Urethrotomy), 58.1 (Urethral meatotomy), 58.31 (Endoscopic excision or destruction of lesion or tissue of urethra (includes fulguration of urethral lesion), 58.39 Other local excision or destruction of lesion or tissue of urethra (includes excision of: congenital valve of urethra, lesion of urethra, stricture of urethra, urethrectomy), 58.6 Dilation of urethra (includes dilation of urethrovesical junction; passage of sounds through urethra; removal of calculus from urethra without incision), 60.95 (Transurethral balloon dilation of prostatic urethra)

Diagnosis of proctitis: 558.1 (Gastroenteritis and colitis due to radiation)

Diagnosis of cystitis: 595.x (Cystitis), 595.82 (Irradiation cystitis).

Diagnosis of hemorrhagic cystitis: 599.71 (Gross hematuria), 595.82 (Irradiation cystitis), 596.7 (Hemorrhage Into Bladder Wall)

Diagnosis of rectal hemorrhage: (569.3) (Bleeding, rectal)

Blood transfusions: CPT code: 36430, HCPCS: P9038 (Red blood cells, irradiated, each unit), P9022 (Red blood cells, washed, each unit), P9021 (Red blood cells, each unit), P9016 (Red blood cells, leukocytes reduced, each unit), P9011 (Blood (split unit), specify amount4), P9010 (Whole blood, for transfusion, per unit), C1018 (Blood, leukoreduced, irradiated, each unit), C1016 (Blood, leukoreduced, frozen/deglycerol/washed, each unit), C1010 (Blood, leukoreduced, CMV negative, each unit), P9039 (Red blood cells, deglycerolized, each unit), C1011 (Platelet, HLA-matched leukoreduced, apheresis/pheresis,each unit), P9040 (Red blood cells, leukocytes reduced, irradiated, each unit)

Appendix ii. ICD-9, CPT-4, and HCPCS Codes to quality of care for prostate cancer.

Pretreatment imaging: CPT Code: 74150 (CT abdomen w/o contrast), 74160 (CT abdomen w/contrast), 74170 (CT abdomen w/o & w/contrast), 78306 (Bone Scan, Whole Body)

Use of conformal radiotherapy treatment planning: CPT Code: 77295 (conformal planning), 77301 (IMRT Plan (after CT imaging)), G0178 (IMRT planning)

Use of high-energy (> 10 MV) photons: CPT Code: 77404-06, 77409-11or 77414-16

Use of custom immobilization during radiotherapy: CPT Code: 77334

Completion of two follow-up visits with radiation oncologist in first posttreatment year: CPT Code: 9921x, 9922x, 9923x, 9924x, 9925x, 9938x, 9939x

Consultation with a urologist or radiation oncologist: CPT Code: 9920x, 9924x

GnRH Agonists: HCPCS codes J9202 (Goserelin acetate implant, per 3.6 mg), J9202 (Goserelin acetate implant, per 19.8 mg), (J1950 (Injection, leuprolide acetate (for depot suspension), per 3.75 mg), J9217 (Leuprolide acetate (for depot suspension), 7.5 mg), J9218 (Leuprolide acetate, per 1 mg), J9219 (leuprolide acetate implant 65 mg)

PSA: HCPCS Codes: 84153 (Prostate Specific Antigen (PSA); total), 84154 (Prostate Specific Antigen (PSA); free)

Cystoscopy: CPT codes: 52000 (Cystoscopy), 52005 (Cystoscopy and Ureter Catheter Cystouretheroscopy, with ureteral catheterization, with or without irrigation, instillation, or ereteropyelography, exclusive of radiologic service), 52007 (Cystoscopy and biopsy cystourethroscopy, with ureteral catheterization, with or without irrigation, instillation, ork ureteropyelography, exclusive of radiologic service; with brush biopsy of ureter and/or renal pelvis), 52204 (Cystoscopy with Biopsy(s), 52250 (Cystoscopy and radiotracer, Cystourethroscopy with insertion of radioactive substance, with or without biopsy or fulguration), 52260 (Cystoscopy and treatment, Cystouretheroscopy, with dilation of bladder for interstitial cystitis; general or conduction (spinal) anesthesia), 52265 (Cystoscopy and treatment, Cystourethroscopy, with dilation of bladder for enterstitial cystitis; local anesthesia), 52270 (Cystoscopy and revise urethra, Cystourethroscopy, with internal urethrotomy; Female), 52275 (Cystoscopy and Revise Urethra, Cystourethroscopy, with internal urethrotomy; Male), 52276 (Cystoscopy and treatment, Cystourethroscopy with direct vision internal urethromy), 52277 (Cystoscopy and treatment, Cystourethroscopy, with resection of external sphincter (sphincterotomy), 52281 (Cystoscopy and treatment, cystourethroscopy, with calibration and/or dilation of uretheral stricture or stenosis, with or without meatotomy, with or without injection procedure for cystography; Male or Female), 52283 (Cystoscopy and treatment, Cystourethroscopy, with steroid injection into stricture), 52285 (Cystoscopy and treatment, Cystourethroscopy for treatment of the female urethral syndrome with any or all of the following: Urethreal meatotomy, Urethral Dilation, Internal Urethrotomy, Lysis of Urethrovaginal Septal ibrosis, Lateral Incisions of the bladder neck, and fulguration of polyp(s) of urethra, bladder neck, and/or trigone), 52310 (Cystoscopy and treatment, Cystourethroscopy, with removal of foreign body, calculus, or ureteral stent from urethra or bladder (separate procedure); simple.