Universal Cystoscopy: What is the Evidence?
MSACOG Snow Meeting
Feb 3, 2017

Objectives

- What controversy?
- Why the hesitation?
- Discuss patient safety concerns
- Selective use cystoscopy reasoning
- Benefits of Universal Cystoscopy at time of GYN surgery
- Support for routine if not more liberal use of cystoscopy at time of gynecologic surgery

Nothing to Disclose
How Many Perform Cystoscopy Routinely?
- At least 80-90% of major GYN cases?
- Open hysterectomy?
- Laparoscopic hysterectomy?
- Pelvic organ prolapse procedures?
- Transobturator midurethral sling procedures?
How Many Perform Cystoscopy Routinely?

- At least 80-90% of applicable cases?
- Open hysterectomy?
- Laparoscopic hysterectomy?
- Pelvic organ prolapse procedures?
- Transobturator midurethral sling procedures?

What Controversy?
So What’s the Issue?

- Injury to the LUT is low so routine use of cystoscopy is not common practice
- Severity of delayed injury can be significant
- Impact on both patient and provider can be substantial
- Suggests we take a more liberal use of cystoscopy during GYN procedures

Pettit OBG 1994; 84:318-20

Crux of the Matter...

Can Universal Cystoscopy Improve Outcomes?

What’s at Stake?

Patient Safety
Costs
Patient Safety

LUT Injuries
Visual Detection
- Gynecologic operations most common antecedent procedure – 75% (Ibeanu, OBG 2009)
- Intraoperative visual detection LUT injury without cystoscopy: (Teeluckdharry, OBG 2015)
  - ureter – 10%
  - bladder 79%
- 85% ureteral injuries detected postoperatively (Dowling, Jard 1986)
- Makes it difficult to predict risk for injury on judgment alone

Reported Injury Rates
Frequently Quoted in Articles
- Bladder injuries: 0.2 – 1.8% (Bia IUJ 2006, Liapis IUJ 2001, Dandolu IUJ 2003)
- Ureteral injuries: 0.03 – 1.5% (Härkki-Siren OBG 1998)
- Higher with prolapse procedures (Braun OBG 2009)
- Asymptomatic ureteral injury
  - 2/15 (Conger OBG 1994)
  - 2/8 St. Martin J Urol 1999
Reported Injury Rates
Difference in Study Design
- **Retrospective Meta Analysis**: (Teeluckdharry OBG 2015)
  - Bladder injury rate: 0.8%
  - Ureteral injury rate: 0.3%
- **Prospective Studies**: (Ibeanu OBG 2009)
  - Bladder injury rate: 2.9%
  - Ureteral injury rate: 1.8%

Unrecognized Ureteral Injury
- Multicenter RCT
  - 174 pts followed for 6 months
  - Primary outcome: ureteral jet visualization
  - Secondary outcomes:
    - Mean total diagnostic cystoscopy time: 4-4.8 min
    - 3 obstructions identified (none postop)
    - Concept here—no complications, short op time, 3 injuries detected and not expected — even though this study was looking at improvement of visualization

Advantages of Intraoperative Recognition
- Intraoperative injury recognition and repair decreases postoperative morbidity (Badenoch BrJUrol 1987)
- Minimizes loss of kidney function (Dowling J Urol 1984)
Consequences of Delayed Diagnosis

- Silent renal death
- Need for nephrectomy
- Fistula formation
  - Urethro vaginal
  - Vesical vaginal
  - Ureterovaginal
- Peritonitis from leaking urine with delayed repair
  - Post op ileus, fever
- Socioeconomic implications
- Increased litigation risk

An Ounce of Prevention...

Increased Risk for Injury

- Previous pelvic surgeries
  - Prior C/S - 2-3 fold increase
- Endometriosis
- LUT anomalies
- Prior pelvic radiation
- Large pelvic mass/uterus
- Obesity

Ibeanu OBG 2009; 113:6
Vakili AOG 2005; 192:1599
Surgical Procedure Types Associated with Increased Risk for Injury

- Pelvic malignancies
- Pelvic reconstructive procedures
- Laparoscopic hysterectomy
  - May decrease with experience (Lafay Pillet Hum Reprod 2009)
- Low/intermediate volume surgeons (Morgan FPMRS 2016, Sandberg OBG 2012)

Silent Ureteral Obstruction

- Handa IUJ 2001
- Retrospective from Jan 1997 – Dec 1999
- 157 POP procedures with cystoscopy
- Results:
  - 5 cases unable to confirm patent ureters
  - 4/5 determined to be preexisting
  - 2/4 cases long-standing advanced proctocentitia
- Consider preoperative imaging in cases of advanced and longstanding POP.

Preoperative Ureteral Stents

- Chou 2009 RCT
  - 1583 prophylactic stents
    - 19 (1.2%) ureteral injuries
  - 1558 without stents:
    - 17 (1.09%) ureteral injuries
**Preoperative Ureteral Stents**

**Conclusions**

- Placement of ureteral stents does not eliminate ureteral injury
- May be beneficial for known or suspected cases of significant pelvic adhesions/fibrosis
- May improve intraoperative detection of the injury site decreasing severity of injury
- No substitute for careful surgical technique and visualization retroperitoneal ureter

Chou IUJ 2009; 20:689

**Preoperative Ureteral Stents**

- Schimpf BJOG 2008
- Decision Analysis Model: cost-effectiveness of routine preop ureteral stents
  - Benign and radical hysterectomies
  - DRG, CPT US Medicare pts
  - Cost-effective when injury rate > 3.2%
  - Cost savings minimal at common levels of injury

Schimpf BJOG 2008

**Illuminated Stents**

- Redan 2009
- 151 complex pelvic pathology with illuminated stents
  - 45 laparoscopic colorectal
  - 49 G1N hysterectomies
  - 57 pelvic adhesions
- 0 ureteral injuries with stents
- 2 ureteral injuries same time period without stents
- Lighted stents have potential to decrease ureteral injury in complicated cases

Redan JA, JLS. 2009;13(2):138-41
illuminated Stents

Stryker UKIT

Contrast Agents
Bladder Instillation

- **Infant formula**
  - Readily available in L&D
  - Bladder integrity only

- **Methylene blue**
  - 2-4 drops in 300-500 ml
  - Risk for methemaglobinemia doses > 7mg/kg

- **10% Dextrose**
  - Increased visual contrast
  - Increase UTI risk (Siff, AJOG 2016; 215:74e1)

Contrast Agents
IV or Oral Administration

- **Indigo carmine**
  - Raw material no longer available since 2015

- **Sodium fluorescein 10%**
  - Used in optic angiography
  - IV: 0.25-0.50 ml
  - Yellow-green jets in 6 min (Doyle OBG 2015; 125:548)

- **Phenazopyridine (AZO)**
  - PO: 100 mg 30-60 min preop
  - Less predictable
  - Orange-red jets can appear bloody

- **Vitamin B complex**
  - PO: 3 tablets 1-4 hr preop
  - Bright yellow jets
  - Unpredictable. Need to plan ahead
Contrast Agents
Improve Efflux
- Fluid bolus
- Reverse Trendelenburg
- Lasix 10-20 mg.

Costs

Added Cost of Cystoscopy
- 2003 Ferro et al AJOG
  - $54.42 per case
  - Not including anesthesia
- 2001 Visco et al OBG
  - 1998 USD = $125 per case
  - $183.20 in 2016 USD
  - Additional equipment needs
  - Additional training of gynecologists
  - Lost operating room time
  - “Repairing” injuries that would have healed spontaneously

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Can Routine Cystoscopy be Cost Effective?

Visco et al 2001
Decision analysis model
1998 US dollars
“Lower” costs of ureteral injury repair identified and treated at time of hysterectomy vs. “higher” costs of a delayed diagnosis
Breakeven point – ureteral injury rate where cost differential is 0

Visco, A., OBG 2001;97:685

Cost of Cystoscopy 1998 USD = $125
2016 USD = $183.30 (www.saving.org/inflation)

At 0.2% ureteral injury rate:
- Cystoscopy adds $108/case
- $54,000 additional cost/ureteral injury identified

At 2.0% ureteral injury rate:
- Cystoscopy saved $44/case
- Cost savings $2200/ureteral injury identified

Visco, A., OBG 2001;97:685
Can Routine Cystoscopy be Cost Effective?

Visco et al 2001

- Conclusion
  - Cost Effective when
    - Rate exceeds 1.5% in TAH
    - Rate exceeds 2.9% VH or LAVH
  - Only ureteral injuries considered
  - Did not account for socioeconomic costs or litigation

Costs of Litigation

Gilmour et al 2005

- RR litigation from LUT injury following GYN surgery in Canada

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<th>Procedure</th>
<th>Prevalence of LUT (%)</th>
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<td>63/792,201 (0.03)</td>
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<td>Hysterectomy only</td>
<td>315/70,042 (0.74)</td>
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Gilmour OBG 2005; 105:109-14
## Litigation

**Gilmour et al 2005**

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<td>515/70,104 (0.74)</td>
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<td>5/121 (4.1)</td>
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*Overall 11-fold increase*

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**Arguments Against Use of Universal Cystoscopy**
Arguments Against Use of Universal Cystoscopy
- Risk for LUT injury is very low
- Increases operative time
- Privileging not universal
- Additional cost to the system
- Increased UTI risk
- Detection of clinically insignificant injuries
- Complications from procedure
- Normal cystoscopy does not negate injury
- Has not decreased the postop detection rate

What is Responsible for the Low Sensitivity?
- Thermal injuries
- Ureteral vascular compromise
- Partial crush injury
- Suture necrosis
- Denuded detrusor
- All may reveal normal ureteral jets/bladder epithelium at intraoperative cystoscopy

Disadvantages to Cystoscopy
- Increased operative time
- Cost
  - $54.42 per case
- Increased UTIs
- Bladder trauma
- Detection of clinically insignificant injuries
- Complications from procedure

Ferro AJOG 2003; 189:354
Barriers to Performing Cystoscopy

- Lack of training
  - Becoming less of an issue
  - Proficiency comes out of repetition
- Privileging
  - Some hospitals will not grant privileges to gynecologists
- Extra time
- Lack of reimbursement for added procedure

Risks to Cystoscopy

- Serious complications rare
  - 0 complications in 1270 cystoscopies (Wiskind, JPelSurg 1995)
  - 0 complications 251 cystoscopies in 1982 hysterectomies (Sandberg OBG 1982)
  - 1/101 injury from inadvertent high temperature distention fluid (Ferro AJOG 2003)
- Detection of self-limited injuries (e.g. absorbable suture) not clinically significant
- Reaction to contrast agents (Graziano IUJ 2005)
- Potential increased risk of UTIs

Studies Supporting a More Selective Use of Cystoscopy
Suggesting Selective Use
Propst 2014
- Propst et al, 2014 OBG
- Routine cystoscopy w robotic hysterectomies
  - 232 robotic hysterectomies
  - 225 robotic hysterectomies with cystoscopy
  - 1.7% ureteral injury rate
  - 0 bladder injuries

Supporting Selective Use
Propst 2014
- 5 abnormal cystoscopies:
  - 3 false positives
    - All received stents
    - No injuries identified
  - 2 normal intraoperative cystoscopies presented with subsequent ureteral injuries

Supporting Selective Use
Propst 2014
- Sensitivity 50%
- Specificity 98.6%
- PPV 40%
- Conclusion: Routine cystoscopy not recommended due to poor sensitivity and poor positive predictive value
Suggesting Selective Use
Sandberg et al 2012

- Sandberg OBG 2012
- Retrospective study – cystoscopy use and ability to detect LUT injury at time of hysterectomy
- 1982 hysterectomies 1/2009-12/2010
  - 251 (12.7%) had concurrent cystoscopy
  - 19 LUT injuries (0.95%):
    - 14 (0.71%) bladder injuries
    - 5 (0.2%) ureteral injuries

No complications from cystoscopic procedure

Suggesting Selective Use
Sandberg et al 2012

- Cystoscopy did not aid in detection of any LUT injuries
  - 14 bladder injuries: 10 were identified intraoperatively by blood tinged urine or fluid in operative field
  - 2/4 delayed bladder injuries – cystoscopy was performed and found normal
  - 5 ureteral injuries. Cystoscopy not performed and all were detected postoperatively
  - 3/4 delayed bladder injuries resulted in fistulas

Suggesting Selective Use
Sandberg et al 2012

- Conclusions:
  - 5 ureteral injuries: Cystoscopy not performed and all were detected postoperatively
  - Given low incidence LUT injury and low sensitivity for cystoscopic detection, unclear to recommend universal cystoscopy but threshold to perform should be low.
  - Associated with ureteral injury:
    - Low volume surgeon
    - Laparoscopic or vaginal access
    - Pelvic adhesions
    - May be a role with these factors
What are Potential Advantages of Universal Cystoscopy?

Arguments In Favor of Universal Cystoscopy

- Prompt recognition and repair reducing morbidity and cost
- May decrease risk for fistula formation
- May reduce risk for permanent renal injury
- Added postoperative reassurance
- May decrease risk for litigation
- Underestimation of LUT injuries in retrospective studies
  - Increase in Laparoscopic/Robotic GYN procedures which have higher injury rates
  - Earlier studies weighted towards laparotomies
  - Most ureteral injuries go undetected
  - Become an “expert” in normal cystoscopy
  - Improved comfort with procedure
  - Improved efficiency saves cost

Mattingly, Clin OBG 1978;5:123
Sakellariou EuOBG 2002; 101:179

Resident Exposure

- Resident experience and post-residency plans for diagnostic cystoscopy at time of hysterectomy
- Survey to residents 2015 UK
- Universal diagnostic cystoscopy:
  - Vaginal hysterectomy 12%
  - LAVH 14%
  - Supracervical hysterectomy 0%
  - TAH 2%
  - TLH 27%
- Residents planned to use universal diagnostic cystoscopy more often than practiced in residency

Vaynberg, Womens Health 2015; 11:825
Studies Supporting Universal Cystoscopy Approach

Vakili et al 2005

Prospective from 3 academic sites 2000-2003
- 471 pts with benign disease
- TAH, VH and LAVH (54 POP and or UI procedures)
- 23/471 (4.8%) LUT injuries
- 8 ureteral injuries – 1.7% (3 from USLS)
- 17 bladder injuries – 3.6% (2 – bladder and ureter)
- 30% LUT injuries detected prior to cystoscopy
  - 12.5% ureteral
  - 35.5% bladder
- 1 case detected postoperatively (VVF)

Vakili AJOG 2005; 192:1599

Suggesting Universal Approach

Vakili et al 2005

- incidence of LUT injuries underestimated
  - Higher than previous retrospective series
  - LAVH numbers were low in this series
- 30% detected prior to cystoscopy
  - Surgeons aware of study objective
  - Ureteral peristalsis persisted 5/6 ureteral injuries at TAH – poor predictor

Vakili AJOG 2005; 192:1599
Suggesting Universal Approach

Vakili et al 2005

- No complications from cystoscopy or cases of pyelonephritis
- RR 6.7 for ureteral injury with prolapse surgery
- RR 4.2 for bladder injury with SUI surgery
- Increased risk concurrent injury when one injury is present
- Recommend a more liberal use of cystoscopy

Suggesting Universal Approach

Ibeanu et al 2009

- Ibeanu 2009
- Prospective, continuation of LSU RCT
  - 839 pts
- Injuries:
  - Ureter 15/839 (1.8%)
  - Bladder 24/839 (2.9%)
  - Simultaneous ureter = bladder in 3 cases
  - Cumulative LUT injury rate 39/839 (4.3%)

Suggesting Universal Approach

Ibeanu et al 2009

- Cystoscopy detected all LUT injuries except:
  - 1 case of VVF – normal intraoperative cystoscopy
  - 25.6% detected by visual inspection
  - 1/15 ureteral injuries
  - 9/24 bladder injuries
- Subnormal ureteral efflux does not suggest injury but requires further investigation
- The adoption of universal cystoscopy after all hysterectomies is recommended
Studies Comparing Selective to Universal Approach

Selective vs Routine Cystoscopy

- 2015 Systematic Review – routine vs. selective use
- Rates of LUT injury identified intra and post operatively
- 79 mostly retrospective studies
- Intraoperative detection:

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<th>Ureteral injuries/1000</th>
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<td>Routine Cystoscopy</td>
<td>20.0</td>
<td>11.3</td>
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<tr>
<td>Selective Cystoscopy</td>
<td>5.8</td>
<td>0.4</td>
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p<0.001  p<0.001

- Postoperative detection:

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<td>Selective Cystoscopy</td>
<td>0.8</td>
<td>1.6</td>
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p=NS  p=0.054 NS

Teeluckdharry, B., OBG 2015; 126(6):1161-69
Selective vs Routine Cystoscopy

Conclusion:
- Cystoscopy provides a clear advantage with intraoperative detection of LUT injuries
- 5 fold increased detection in pelvic reconstruction procedures and lap hysterectomy
- Does not appear to have much effect on the postoperative injury detection rate
- Exception: pelvic reconstructive procedures would benefit (p=0.03)

Teeluckdharry, B., OBG 2015; 126(6):1161-69

Suggesting Universal Approach

Chi et al 2016

Retrospective study flanking implementation of an universal cystoscopy policy in 2008
- 973 hysterectomies pre-policy
  - 36% had cystoscopy
- 1849 hysterectomies post-policy
  - 86% had cystoscopy
- Overall LUT injury rate:
  - 25/973 (2.6%) pre-policy
  - 34/1849 (1.8%) post-policy
  \[ p=0.21 \]

Chi OBG 2016; 127:369

Suggesting Universal Approach

Chi et al 2016

Delayed urologic injuries decreased
- 7/973 (0.7%) pre
- 2/1849 (0.1%) post  \[ p=0.01 \]
- 4/9 delayed injuries had normal cystoscopy
  - 2 pre and 2 post policy
  - 2 ureteral obstruction, 1 cystotomy, 1 UVF
- 4 VVF pre, 0 VVF in post
  - 90% VVF result from benign GYN (Lee OBG 1988;72:313–9)
- Hospital charges nearly doubled for delayed LUT injuries but insurance payments remained the same
- UC improves patient safety and reduces costs

Chi OBG 2016; 127:369
Can’t We Set up a RCT to Answer This Question?

Feasibility of a Multicenter RCT

- LUT injuries relatively rare
- In order to detect meaningful difference between detection of postoperative LUT injury / 1000 surgeries:
  - @ 80% Power
  - Requires 25,500 in each group
- Even if feasible, statistical significance may not equate to clinical significance

Society Guidelines

- ACOG 2007
  - Procedures with “high risk” for complications may benefit from cystourethroscopy – prolapse or incontinence
  - Routine use requires further study
- AAGL 2012
  - Routine use after all laparoscopic total hysterectomies
- AUA 2009
  - Standard: Intraoperative cystourethroscopy should be performed in all patients undergoing sling surgery
- NQF 2063 – Proposed by AUGS
  - Percentage of patients having cystoscopy with anterior and/or vaginal vault repairs
Summary

- No established guidelines for universal cystoscopy
- Improved intraoperative detection of LUT injuries
- Less so with postoperative detection
- Morbidity and additional costs to cystoscopy are minimal
- Risk of LUT injury may be higher with laparoscopic hysterectomies, pelvic reconstruction procedures
- A very liberal use if not routine cystoscopy is prudent
- Cystoscopy is no substitute for good judgment and meticulous surgical technique

References

References

- Vaynberg D., Resident experiences with and post-training plans for cystoscopy at the time of hysterectomy. Western J Med. 2015 Nov;11(1):825-31. doi: 10.2176/westj.2015.11.1.825-

References

- Redan JA, McCarus SD. "Protect the ureters." JSLS. 2009 Apr-Jun;13(2):139-41.

References


References

So What’s the Issue?

- Wiskind and Thompson 1995
- Retrospective review all ureteral injuries between 1990 – 1994
- 1511 Major GYN procedures “at risk”
  - No laparoscopic procedures
  - 1270 had intraoperative cystoscopy
- 7 ureteral injuries – 5 unsuspected (0.39%)
- Conclusion: Routine use of indigo carmine and cystoscopy will reduce or eliminate all unrecognized ureteral injuries

Levels of Prevention

- Primary – avoiding injury
  - Knowledge of pelvic anatomy
  - Surgical restoration of normal anatomy
  - Meticulous surgical technique
  - Preoperative imaging for suspected LUT anomalies
- Secondary – Recognition and repair of injury
  - Warning signs
  - Cystoscopy
- Tertiary – Postoperative diagnosis and management of injury