Evidence has shown that ultrasonography (US) is unreliable for the diagnosis of undescended testis (UDT). Despite this, referring physicians (RP) continue to adopt this practice. US is the most common investigation ordered by the RP when uncertain of testicular position before referring patients to a pediatric urologist (PU).

Previous research has shown that a positive US does not change the surgical management of boys with UDT.

**Background**

**Objectives**

- To determine agreement between RP and PU regarding diagnosis of UDT
- To calculate the accuracy of US as a diagnostic test for UDT

**Methods**

**Study Design:**
- Prospective data collection from 2012-2013
- Data managed using Research Electronic Data Capture (REDCap) software
- HIREB: 12-659-D

**Inclusion Criteria:**
- Boys referred to McMaster Children’s Hospital for UDT

**Exclusion Criteria:**
- Patients who did not have US as part of their UDT evaluation

**Data Collection:**
- Diagnosis of RP
- PU impression of testicular position by physical examination
- US findings

**Results**

**Figure 1:** Flow Diagram of Included Patients

- 228 Patients Entered
- 134 Patients with US
- 94 Patients without US
- 182 UDT Cases Included
- 86 Unilateral
- 48 Bilateral

**Figure 2:** Agreement Between PU and RP Diagnosis

- 57% Confirmed UDT
- 43% Retractile

**Figure 3:** Agreement Between US and PU Diagnosis

- 62% Agree
- 38% Disagree

Kappa = -0.2 (95% CI: -0.3 — -0.1)

**Measure of Performance**

<table>
<thead>
<tr>
<th>Measure of Performance</th>
<th>Result</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>92%</td>
<td>84-97%</td>
</tr>
<tr>
<td>Specificity</td>
<td>11%</td>
<td>6-18%</td>
</tr>
<tr>
<td>Positive Predictive Value</td>
<td>44%</td>
<td>37-52%</td>
</tr>
<tr>
<td>Negative Predictive Value</td>
<td>65%</td>
<td>38-86%</td>
</tr>
<tr>
<td>Positive Likelihood Ratio</td>
<td>1.0</td>
<td>0.9-1.1</td>
</tr>
<tr>
<td>Negative Likelihood Ratio</td>
<td>0.7</td>
<td>0.3-1.9</td>
</tr>
</tbody>
</table>

**Discussion**

**Agreement on Diagnosis:**
- Agreement between RP and PU diagnoses of UDT was very low.
  - Only 43% of all referrals were for true UDT.

**Ultrasound Performance:**
- US results agreed with PU physical exam at a rate lower than random chance.
  (Less than tossing a coin!)
- Positive likelihood ratio = 1
- The probability of a child having UDT is the same as not having UDT when US indicates UDT.

**Conclusion**

- These results show that US performs poorly as a diagnostic test to detect UDT in young boys, with a high percentage of false-positive results.
- US should not be used for this purpose as it creates confusion and anxiety for patients and their families.
- Unnecessary utilization of a diagnostic test is a burden to the Canadian healthcare system both in cost expenditure and use of diagnostic imaging resources.

**Future Direction**

A cost-utility analysis should be done to demonstrate unnecessary health care expenditures used for this test, as well as the burden to families and stress caused by false-positive ultrasounds.

Efforts will be made to inform primary care providers of these findings and to counsel them against ordering ultrasounds.

As a limitation, this study may not have captured patients who had US for query UDT which showed normally descended gonads, and consequently were never referred to our centre.
Introducing the Research Electronic Data Capture System: An Innovative Data Management Tool in Pediatric Urology Research

Kanters DM\textsuperscript{1,2}, Pemberton J\textsuperscript{1,2}, DeMaria J\textsuperscript{1,2}, Braga LH\textsuperscript{1,2}

\textsuperscript{1} McMaster University, Dept. of Surgery, Division of Urology
\textsuperscript{2} MPSRC, McMaster University, Dept. of Surgery

**Background**

A cost-effective method for large-scale multi-centre data collection and management is needed in pediatric urology due to the nature of current research questions.

Electronic Data Capture (EDC) is well-established as an improved method to conduct clinical research compared to paper-based forms.

**Objectives**

- To introduce an innovative new system for building and managing online surveys and databases: Research Electronic Data Capture (REDCap)
- To promote the use of REDCap as an improved tool for large-scale data management in pediatric urology research

**Methods**

**Review of Literature:**

- Articles citing the use of REDCap listed on the REDCap website
- Supplemented with a keyword search of “REDCap” and “Research Electronic Data Capture” in the MEDLINE® database from 1946- Dec 2012

**Inclusion criteria**

- Articles reporting the use of REDCap to manage participant data in a research study or survey
- Limited to surgery, urology or pediatric urology

**Data Collection**

For each article citing the use of REDCap, we recorded:

- Field of Study
- Type of Study
- Enrollment
- Funding
- Number of Centres

**Results**

<table>
<thead>
<tr>
<th>Field of Study</th>
<th>Number of Studies Using REDCap (n = 149)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery</td>
<td>56/149 (38%)</td>
</tr>
<tr>
<td>Urology</td>
<td>4/56 (7%)</td>
</tr>
<tr>
<td>Pediatric Urology</td>
<td>2/56 (4%)</td>
</tr>
</tbody>
</table>

*Table 1: Field of Study of Research Articles Using REDCap*

<table>
<thead>
<tr>
<th>Study Design</th>
<th>Number of Studies (n = 56)</th>
<th>Enrollment (Min-Max)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prospective or RCT</td>
<td>20 (36%)</td>
<td>22-1664</td>
</tr>
<tr>
<td>Retrospective</td>
<td>30 (54%)</td>
<td>21-9171</td>
</tr>
<tr>
<td>Surveys</td>
<td>6 (11%)</td>
<td>47-1356</td>
</tr>
</tbody>
</table>

*Table 2: Enrollment in Surgical Studies Using REDCap*

**Conclusions**

- REDCap will facilitate large-scale, multi-centre clinical research in pediatric urology.
- REDCap use is growing rapidly in small- and large-scale clinical research.
- There has been modest use of this tool in pediatric urology research to date.

**Why REDCap?**

**Accessibility**

- Intuitive and user-friendly
- Data-entry interface accessible using laptops, tablets, or smartphones
- Extensive training materials available online
- REDCap software available at no cost

**Data Quality and Security**

- Automatic data validation during data entry
- Audit trails for tracking data export or manipulation
- Automated export procedures to common statistics software that protect sensitive patient identifiers
- Secure, encrypted, and HIPAA compliant

**Prevalence**

- 534 institutions worldwide use REDCap
- At McMaster Children’s Hospital in Pediatric Urology, REDCap is currently used to manage 5 prospective clinical research studies:
  - Hydronephrosis (n=250)
  - Undescended Testis (n=168)
  - Hypospadias (n=202)
  - Urotherapy RCT (n=48)
  - ALPHA RCT (n=46)

**Figure 1:** Funding Status of Studies Using REDCap

**Figure 2:** Number of Centres in Studies Using REDCap

**Figure 3:** Map of REDCap Consortium Partners
Hypospadias Outcomes Long-term Database (HOLD): Preliminary Results

Braga LH1,2, Kanters DM1,2, Pemberton J1,2, DeMaria J1,2

1 McMaster University, Dept. of Surgery, Division of Urology
2 MPSRC, McMaster University, Dept. of Surgery

Background
There is a paucity of high-level evidence on the long-term outcomes of hypospadias repair. Researchers lack standardized measurement tools and do not seem to agree on how to define patient characteristics, such as meatal location and severity of hypospadias.

Objectives
To analyze a prospective database of hypospadias repair patients, examining potential risk factors for the formation of urethrocutaneous fistula (UCF).

Methods
Study Design:
• A secure, online, prospective database was created using Research Electronic Data Capture (REDCap).
• HIREB: 09-519-D

Eligibility Criteria:
• Patients who underwent primary Tubularized Incised Plate (TIP) repair at McMaster Children’s Hospital were included.

A Priori Risk Factors:
• Patient age at surgery
• Severity of defect (meatal position)
• Pre-operative testosterone stimulation (PTS)
• Glans and urethral plate (UP) width
• Surgeon assessment of UP quality including depth and elasticity
• Frequency of UCF

Definition of Urethral Plate Quality:
• Good: moderate/deep glans groove, supple/elastic, width >6mm
• Poor: shallow glans (no groove), inelastic, width <6mm

Statistical Analysis
• A Student’s t-test was used to compare mean UP width pre-incision and age between patients who developed UCF vs. those who did not.
• UP width pre-incision of patients with UCF was age-matched with 3 controls without UCF (±1mo).

Results
• The overall UCF rate was 6.5% (N=93/156).
• Reasons for exclusion were: not TIP (N=46), redo (N=5), follow-up pending (N=7), and missing data (N=5).

Figure 5: Flow Diagram of Included Patients
156 Patients Underwent Correction
93 Eligible
63 Excluded

Figure 6: Comparison of UCF Rates by Severity of Defect
Distal 2 UCF (3%)
Midshaft 1 UCF (7%)
Proximal 3 UCF (21%)

The rate of UCF in patients with midshaft and proximal defects was higher than in those with distal defects (15% vs. .3%, p = 0.03).

Table 1: Comparison of UCF Rate in Patients with Distal vs. Proximal Defects, Stratified by PTS

<table>
<thead>
<tr>
<th>Severity</th>
<th>PTS</th>
<th>Total No.</th>
<th>No. UCF (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distal</td>
<td>Yes</td>
<td>8</td>
<td>0 (0%)</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>56</td>
<td>2 (3%)</td>
</tr>
<tr>
<td>Proximal/Midshaft</td>
<td>Yes</td>
<td>18</td>
<td>4 (22%)</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>9</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

Table 2: Characteristics of Patients with UCF and No UCF

<table>
<thead>
<tr>
<th></th>
<th>No UCF</th>
<th>UCF</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean UP Width (mm)</td>
<td>7.1±1.4</td>
<td>5.5±2.5</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Mean Age (mos.)</td>
<td>25.3±22.2</td>
<td>15.0±2.7</td>
<td>0.2</td>
</tr>
</tbody>
</table>

Table 3: Comparison of UP Width Between Patients with UCF and Age-Matched controls

<table>
<thead>
<tr>
<th></th>
<th>No UCF (age-matched controls)</th>
<th>UCF</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean UP Width (mm)</td>
<td>7.5</td>
<td>5.0</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

Conclusion
• Characteristics of the UP, predominantly the pre-incision width, seem to be associated with the development of UCF in patients undergoing TIP repair.
• Analysis of a larger number of patients is needed to corroborate these preliminary findings.

Future Direction
• To adequately assess the cosmetic and functional outcomes of this surgical procedure, it is necessary to follow patients through adolescence.
• Due to the logistical difficulty of a 15-year follow-up period, it is necessary to include multiple centres in a prospective international database.
• We plan to expand the HOLD database to centres across Canada, the USA, South America, and Europe.

Getting Involved
If you are interested in becoming a participating centre in the HOLD study, please contact Julia Pemberton at pemberj@mcmaster.ca or visit our website: fhs.mcmaster.ca/mpsrc/hold.html
### Background

**The Problem**
- Urotherapy is the standard, nonsurgical, nonpharmacological treatment for children non-neurogenic lower urinary tract dysfunction (NLUTD)/dysfunction elimination syndrome (DES)
- Urotherapy modalities vary by setting, curriculum and length of treatment
- Most effective modality undetermined, few controlled trials published

**Research Question**
Among children aged 6 to 10 with NLUTD/DES, is a 1 hour group urotherapy session about bladder re-training and establishing healthy bowel habits more effective than the standard urotherapy provided in pediatric urology clinic: 1) Improving NLUTD/DES symptoms 2) Improving quality of life.

**Pilot Objectives**
- Determine the feasibility of
  1. Implementing group urotherapy sessions
  2. Recruiting patients for a controlled trial
  3. Using the PinQ and Vancouver NLUTD/DES questionnaires to evaluate urotherapy from the child’s perspective
  4. Complying with study protocol

### Methods

**Study Design:**
- Prospective RCT pretest/posttest design
- Randomization: Centralized computerized simple randomization 1:1 no blocks

#### Protocol
- Children aged 6-10 diagnosed with NLUTD/DES
- Consent, Baseline measurements
- Control Group
- Study Group
- Individual Urotherapy Session
- Group Urotherapy Session
- Session occurs within 6 weeks of consent
- Completion of PinQ & Vancouver NLUTD/DES Questionnaires
- Completion of Evaluation Forms by Parent and Child
- 3 Months from either Urotherapy session
- Timeline of 3 month follow-up (n = 2)

### Results

**Patient Screening from: August 14 2012 - March 6 2013**
- 316 Patients Screened
- 58 Eligible 18.4%
- 258 Not Eligible 81.6%
- 42 Recruited 72.4%
- 13 Declined 22.4%
- 3 Missed 5.2%

#### Reasons for Ineligibility
- Non-English Speaking 0.4%
- Already received Urotherapy 10.5%
- High Grade HN 1.5%
- Did not meet diagnostic criteria 18.4%
- Age > 10 years 22.6%
- Age > 6 years 36.8%
- VUR 3.4%
- Learning Disability 2.6%
- Other disorder 3.6%

**Note:** Some patients were ineligible due to multiple reasons.

#### Baseline Demographics August 14 2012 - March 6 2013

<table>
<thead>
<tr>
<th>Sex</th>
<th>Individual (n=23)</th>
<th>Group (n=19)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>21 (91%)</td>
<td>15 (79%)</td>
</tr>
<tr>
<td>Male</td>
<td>2 (9%)</td>
<td>4 (21%)</td>
</tr>
<tr>
<td>Age 6-8</td>
<td>16 (70%)</td>
<td>14 (74%)</td>
</tr>
<tr>
<td>9-10</td>
<td>7 (30%)</td>
<td>5 (26%)</td>
</tr>
</tbody>
</table>

#### Reason Followed in Urology Clinic

<table>
<thead>
<tr>
<th>Reason Followed in Urology Clinic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daytime Wetting</td>
</tr>
<tr>
<td>Nighttime wetting</td>
</tr>
<tr>
<td>Recurrent UTI</td>
</tr>
<tr>
<td>Overactive bladder</td>
</tr>
<tr>
<td>Dysfunctional Voiding</td>
</tr>
</tbody>
</table>

**Medications**
- Anticholinergic 1 (4%)
- Prophylactic Antibiotic 2 (9%)
- Stool Softener 2 (9%) (Questionnaire completed by parent/guardian)

#### Status of Enrolled Patients (n=42)

<table>
<thead>
<tr>
<th>Session</th>
<th># of Study Participants</th>
<th># of Non-study Participants</th>
<th>Boys: Girls (Study Participants)</th>
<th>Mean Age of Study Participants (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>3</td>
<td>0</td>
<td>1:2</td>
<td>7.33 ± 1.53</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>0</td>
<td>2:0</td>
<td>7.50 ± 0.71</td>
</tr>
<tr>
<td>3</td>
<td>2</td>
<td>0</td>
<td>2:0</td>
<td>7.00 ± 1.41</td>
</tr>
<tr>
<td>4</td>
<td>3</td>
<td>0</td>
<td>1:2</td>
<td>7.00 ± 1.73</td>
</tr>
<tr>
<td>5</td>
<td>1</td>
<td>2</td>
<td>0:1</td>
<td>7.00 ± 0.00</td>
</tr>
<tr>
<td>6</td>
<td>3</td>
<td>0</td>
<td>0:3</td>
<td>8.67 ± 1.53</td>
</tr>
<tr>
<td>7</td>
<td>4</td>
<td>0</td>
<td>0:4</td>
<td>7.50 ± 1.91</td>
</tr>
</tbody>
</table>

#### Group Session Demographics

- # of Participates: 42
- # of Drop Outs: 5
- Attendance: 95.2%
- Mean Age: 7.33 ± 1.53

#### Primary Reasons for Declining
- Patient preferred individual therapy
- Patient unable to return for group session

#### Group Sessions
- Similar ages (6-8 or 9-10) and same gender groups ran most smoothly
- Demonstrations were very useful for participant engagement
- Parents initiated an open discussion with investigator and other parents after the presentation and children often talked with their peers during this time
- Group sessions were often difficult to coordinate, mainly due to study participant's availability and minimum requirement of 3 participants to run group session

#### Recruitment
- Rate 72.4%

#### Outcome Measurements
- 100% questionnaires completed without difficulty (Assistance by RA/parents as required)

#### Study Protocol
- Dropouts were related to participants being unable to attend group session (n= 3) or not returning for follow-up (n = 2)
- Patients participated in follow up within 2-3 months (n=6), exactly at 3 months (n=6) and outside of 3 months (n=7)
- Timeline of 3 month follow-up difficult to keep if parents had to re-schedule visit

### Conclusion

- Reasons for declining could possibly be mitigated with an online option to attend group session from home
- High recruitment rate of 72.4%
- Final study results will provide insight into the experiences of children with NLUTD/DES as the first study to evaluate urotherapy from the child’s perspective

Funding through Health Professional Investigators Grant (Hamilton Health Sciences)
A National Survey on Determining Perception of Urology as a Specialty by Canadian Medical Students: A Pilot Study at McMaster University

Kim S1, Farrokhyaar F1, Matsumoto E1, Lorenzo A3, Braga LH1

1 McMaster University, Dept. of Surgery, Division of Urology  2University of Toronto, Dept. of Surgery, Division of Urology

Background

Upon inquiring medical students and urologists across Canada, it is evident that Urology is perceived as a male-dominant specialty among other stereotypes. These perceptions may affect the recruitment of trainees. We surveyed medical students in our institution to obtain an objective assessment of their perception of Urology and to determine causes for misperceptions.

Objectives

Primary Objective:
• Assess perception of Urology as a specialty by medical students

Secondary Objectives:
• Determine factors that influence perception of Urology

Methods

Study Population:
• Medical students at McMaster University
• Across all training years (Year 1, Year 2 and Year 3)
• Across all campuses (Hamilton, Kitchener-Waterloo and Niagara)

Survey:
• Piloted among medical students and educational leaders for face and content validity
• 43-item anonymous, cross-sectional, self-report electronic survey
• Included categories:
  • Medical lifestyle (9 items)
  • Societal orientation (9 items)
  • Professional prestige (5 items)
  • Hospital orientation (3 items)
  • Scope of practice (5 items)
  • Role model (4 items)
• Potential factors influencing perception of Urology (selected a priori) for analysis:
  • Age
  • Exposure
  • Family or friends in Urology
  • Gender
  • Years in training
  • Role model

Results

• Response rate = 70% (396 of 567)

Results (Cont.)

Perception of Urology by Medical Students

1) Medical Lifestyle

Overall Lifestyle (Urologist)
- above average, good or excellent: 33%
- average: 44%
- below average, poor or extremely poor: 9%
- do not know: 14%

Overall Lifestyle (Urology Residents)
- above average, good or excellent: 10%
- average: 26%
- below average, poor or extremely poor: 22%
- do not know: 42%

2) Societal Orientation

Gender Balance (Patients)
- slight majority, great majority or all males: 31%
- balanced: 4%
- slight majority, great majority or all females: 2%
- do not know: 63%

Gender Balance (Urologists)
- slight majority, great majority or all males: 27%
- balanced: 73%
- slight majority, great majority or all females: 1%
- do not know: 2%

Gender Balance (Urology Residents)
- slight majority, great majority or all males: 31%
- balanced: 63%
- slight majority, great majority or all females: 2%
- do not know: 4%

3) Professional Prestige

Competitiveness for Entry
- slightly, moderately, or very under competitive: 5%
- fair: 68%
- slightly, moderately, or very competitive: 21%
- do not know: 5%

Income
- good, very good or excellent: 31%
- fair: 63%
- slightly, moderately, or very poor: 1%
- do not know: 5%

4) Hospital Orientation

In-Hospital Care vs Out-Patient Care
- 100 vs 0: 25%
- 75 vs 25: 13%
- 50 vs 50: 27%
- 25 vs 75: 13%
- 0 vs 100: 27%
- do not know: 12%

5) Scope of Practice

Scope of Practice
- slightly, moderately, or very limited: 30%
- average: 31%
- slightly, moderately, or very diverse: 12%
- do not know: 27%

Results (Cont.)

6) Role Model

Involvement in Medical Education (Urologists)
- good, very good or excellent: 23%
- appropriate: 24%
- slightly, moderately or very poor: 31%
- do not know: 16%

Involvement in Medical Education (Urology Residents)
- good, very good or excellent: 31%
- appropriate: 15%
- slightly, moderately or very poor: 38%
- do not know: 31%

Influencing Factors on Perception of Urology

Table 1: Multivariable Logistic Regression Analysis of Factors associated with Positive Perception of Urology

<table>
<thead>
<tr>
<th>Factor</th>
<th>N</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (SD)</td>
<td>24.1</td>
<td>0.116</td>
</tr>
<tr>
<td>Exposure (%)</td>
<td>126 (32.6)</td>
<td>0.001</td>
</tr>
<tr>
<td>Family or Friends (%)</td>
<td>92 (22.5)</td>
<td>0.783</td>
</tr>
<tr>
<td>Gender (Male, %)</td>
<td>146 (35.8)</td>
<td>0.004</td>
</tr>
<tr>
<td>Year 1 (%)</td>
<td>157 (39.5)</td>
<td>0.017</td>
</tr>
<tr>
<td>Role Model (%)</td>
<td>81 (20.9)</td>
<td>0.021</td>
</tr>
</tbody>
</table>

Amount of Exposure

Experience after Exposure to Urology
- Positive: 27%
- Negative: 11%
- Neutral: 61%
- Other: 1%

Conclusion

• Urology is perceived as a specialty with
  • good overall lifestyle as a staff but not as a resident
  • significant gender imbalance in patient, staff and resident population
  • competition for entry
  • good income
  • heavier focus on out-patient care
  • various scope of practice
  • poor staff and resident involvement in undergraduate medical education
• Inadequate exposure to Urology is a potential cause for misperceptions of the specialty
• Improve perception of Urology by
  • increasing exposure to Urology
  • encouraging female students
  • approaching senior students
  • providing mentorship
Prospective Analysis on the Diagnostic Performance of Measurements of the Normally Descended Gonad in Predicting Monorchidism in Boys with Unilateral Non-Palpable Testis

Kim S¹, Farrokhyar F², Lorenzo A³, Braga L¹

¹ McMaster University, Dept. of Surgery, Division of Urology ² McMaster University, Dept. of Clinical Epidemiology and Biostatistics ³ University of Toronto, Dept. of Surgery, Division of Urology

Background

The phenomenon of contralateral compensatory testicular hypertrophy in monorchidism has been observed in the past.

We propose that measurement of contralateral descended testes can be a diagnostic test for monorchidism.

Methods

Inclusion Criteria:

• All patients with cryptorchidism encountered by a single surgeon at McMaster Children’s Hospital

Exclusion Criteria:

• Age ≥ 8 years
• Retractile testes
• Bilateral undescended testes
• Ascending testes

Study Design:

• Prospective study, 2009 – 2013
• Controls:
  • Palpable undescended testes (pUDT)
  • Intraabdominal testes (IAT)
• Cases:
  • Patients intraoperatively confirmed with monorchidism (M)

Data Collection:

• Measured length and width of contralateral descended testes using a caliper
• Calculated sensitivity, specificity and likelihood ratio
• Constructed ROC Curve and determined a diagnostic cut-off size for monorchidism

Results

Inclusion Criteria:

Cryptorchidism n = 324
Excluded n = 181

Palpable UDT n = 58
Dx Laparoscopy n = 85

Monte Carlo
n = 50
n = 35

Results (Cont.)

<table>
<thead>
<tr>
<th>Length (mm)</th>
<th>Likelihood Ratio (LR+)</th>
<th>Length (mm)</th>
<th>Likelihood Ratio (LR+)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;18</td>
<td>6.50</td>
<td>&gt;18</td>
<td>2.30</td>
</tr>
<tr>
<td>&gt;19</td>
<td>7.40</td>
<td>&gt;19</td>
<td>2.80</td>
</tr>
<tr>
<td>&gt;20</td>
<td>10.10</td>
<td>&gt;20</td>
<td>5.80</td>
</tr>
<tr>
<td>&gt;21</td>
<td>11.50</td>
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<td>7.30</td>
</tr>
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<td>&gt;22</td>
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<td>&gt;23</td>
<td>10.10</td>
<td>&gt;23</td>
<td>7.70</td>
</tr>
<tr>
<td>&gt;24</td>
<td>13.00</td>
<td>&gt;24</td>
<td>8.25</td>
</tr>
<tr>
<td>&gt;25</td>
<td>11.50</td>
<td>&gt;25</td>
<td>3.60</td>
</tr>
</tbody>
</table>

Table 4: Likelihood Ratios at Different Cut-Offs for Compensatory Hypertrophy for Predicting Monorchidism in NPTs (Based on M & IAT)

Table 5: Likelihood Ratios at Different Cut-Offs for Compensatory Hypertrophy for Predicting Monorchidism in NPTs (Based on M & pUDT)

Figure 1: Flowchart of Inclusion Process. pUDT = palpable undescended testes, IAT = intraabdominal testes, M = monorchidism

Table 1: Characteristics of Patients

<table>
<thead>
<tr>
<th></th>
<th>M</th>
<th>IAT</th>
<th>pUDT</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>35</td>
<td>50</td>
<td>58</td>
<td></td>
</tr>
<tr>
<td>Mean Age (SD)</td>
<td>28.0 (17.6)</td>
<td>31.3 (18.0)</td>
<td>37.4 (27.2)</td>
<td>0.042</td>
</tr>
<tr>
<td>Mean Length (SD)</td>
<td>24.3 (2.5)</td>
<td>16.5 (3.5)</td>
<td>18.8 (3.6)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Mean Width (SD)</td>
<td>14.3 (1.8)</td>
<td>10.6 (1.9)</td>
<td>11.6 (1.9)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

Table 2: Sensitivity and Specificity of Compensatory Hypertrophy in M Compared to IAT

<table>
<thead>
<tr>
<th>Study</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>More than 10 mm</td>
<td>0.85 [0.72, 0.93]</td>
<td>0.95 [0.85, 0.98]</td>
</tr>
<tr>
<td>More than 15 mm</td>
<td>0.95 [0.87, 0.96]</td>
<td>0.97 [0.94, 0.99]</td>
</tr>
</tbody>
</table>

Table 3: Sensitivity and Specificity of Compensatory Hypertrophy in M Compared to pUDT

<table>
<thead>
<tr>
<th>Study</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>More than 10 mm</td>
<td>0.85 [0.72, 0.93]</td>
<td>0.95 [0.85, 0.98]</td>
</tr>
<tr>
<td>More than 15 mm</td>
<td>0.95 [0.87, 0.96]</td>
<td>0.97 [0.94, 0.99]</td>
</tr>
</tbody>
</table>

Conclusion

• Contralateral descended testes with >20 mm is an ideal cut-off threshold for diagnosing monorchidism with 97% sensitivity, 90% specificity, and 10.1 likelihood ratio
• If validated, this diagnostic test will be an important clinical parameter to possibly:
  • obviate unnecessary diagnostic or exploratory laparoscopy
  • provide preoperative counseling and plan surgical approach in this patient population
Increasing Feasibility of Conducting an RCT in Pediatric Urology: the Effects of Trial Media on Medication Compliance, Recruitment and Parent Perception of Research

Heaman J\(^1,2\), Pemberton J\(^1,2\), Jegatheeswaran K\(^1,2\), Braga LH\(^1,2\)

\(^1\)McMaster University, Dept. of Surgery, Division of Urology
\(^2\)MPSRC, McMaster University, Dept. of Surgery

Background
Research and evidence are lacking on the effects of trial media in recruitment and compliance in randomized controlled trial in pediatric urology.

Objectives
1. To evaluate the effect of an informative trial brochure on a parent’s decision to participate in a randomized controlled trial.
2. To evaluate the effect of an Easy-to-Use medication log on compliance.

Methods
• This was a nested RCT within the ALPHA trial (HiREB \# 09-255)
• At consent all parents were given an informative brochure (Figure 1)
• In August 2010 Version 1 of the medication log was implemented to track medication compliance (Figure 2)
• In November 2012, a new, Easy-to-Use version of the medication log was implemented to improve medication compliance (Figure 3)
• Recorded proportion of returned logs and compliance
• A survey containing 5-point Likert scale questions was then given to parents of enrolled patients to assess the following:
  1. The effects of an informative trial brochure on parents’ decision to participate in the study
  2. Parent’s opinion of Version 1 and Version 2 of the medication log on the following factors:
     i. Parent Preference
     ii. More likely to be filled out accurately
     iii. More likely to be sent back
     iv. The easy-to-use nature of each medication log
• Descriptive statistics were calculated

Methods Continued

Results
• Overall Response Rate: 66% (Figure 4)
  - 35 Enrolled Patients
  - 14 (40%) Active
  - 21 (60%) Inactive
  - 12 (86%) Responded
  - 11 (52%) Responded

Figure 4: Patient Demographics

Table 1: Comparison of Proportion of Returned Logs and Mean Compliance of each Version

<table>
<thead>
<tr>
<th>Log</th>
<th>Proportion Returned</th>
<th>Mean Compliance % (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Version 1</td>
<td>219/266 (82%)</td>
<td>78 (37)</td>
</tr>
<tr>
<td>Version 2</td>
<td>40/44 (91%)</td>
<td>85 (30)</td>
</tr>
</tbody>
</table>

Figure 6: Comparison of Participant Preference for Version 1 or Version 2 of Medication Log

Figure 7: Comparison of Ease of Use Between Version 1 and Version 2

Conclusion
• The trial brochure had a positive effect on parents’ decision to participate in the ALPHA study
• Version 2 of the Medication Log was preferred
  • Considered easy to use
  • More likely to be completed accurately
  • More likely to be returned
• Trial media may be useful to positively impact recruitment rate and proportion of returned medication logs in an RCT in pediatric urology

Funding Through McMaster Surgical Associates
Feasibility of Conducting a Randomized Controlled Trial to Investigate Effects of Antibiotic Prophylaxis on Urinary Tract Infection Rate in Infants with Antenatal Hydronephrosis: The ALPHA Pilot Trial

Braga LH1,2, Pemberton J1,2, Heaman J1,2, DeMaria J1,2, Lorenzo A3

1McMaster University, Dept. of Surgery, Division of Urology 2 MPSRC, McMaster University, Dept. of Surgery 3 University of Toronto, Dept. of Surgery, Division of Urology

Background

Guidelines for use of continuous antibiotic prophylaxis (CAP) for prevention of UTIs in antenatal hydronephrosis (AHN) patients is based on low levels of evidence.

Objectives

To determine the feasibility of conducting a randomized clinical trial evaluating the effect of CAP on UTI rate in infants with grades III-IV AHN over 12 months by evaluating:
- Recruitment rate
- Event (febrile UTI) rate
- Medication compliance
- Follow up schedule compliance

Methods

Study Design:
- Superiority, parallel:
  - Treatment: Oral Trimethoprim prophylaxis 2 mg/kg
  - Control: Oral placebo liquid
- Randomized:
  - Centralized web-based blocked randomization
- Blinded:
  - Patients, investigators, research staff, and outcome assessors
- HiREB # 09-255

Inclusion Criteria:
- Postnatal U/S with High Grade (III,IV) HN and/or ureteric dilatation ≥7mm
- <5 months of age
- Had a VCUG
- Parent or guardian able to speak and understand English and provide informed consent

Exclusion Criteria:
- VUR
- Duplication anomalies (ureteroceles, ectopic ureter)
- PUV, Prune-Belly Syndrome
- Chronic use of CAP
- Allergy to trimethoprim
- Solitary kidney
- Low Grade HN (Grade I, II)
- Co-enrollment in another intervention study

Data Collection:
- Feasibility Data:
  - Eligibility, enrollment, and reason for decline
  - Event rate: frequency of UTI
- Protocol Compliance:
  - Adherence to 12 month F/U schedule:
  - Medication compliance recorded on med logs

Results

- Overall recruitment rate: 59% (Figure 1)
- Event (febrile UTI) rate: 25%
- UTI is more common in patients with Megaureter p=0.04 (Table 2)

Table 1: Characteristics of Patients who Developed UTI

<table>
<thead>
<tr>
<th>Sex</th>
<th>Age (mo)</th>
<th>Baseline AHN Grade</th>
<th>AHN Etiology</th>
<th>Ureter Caliber (mm)</th>
<th>Circ Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>M</td>
<td>6.0</td>
<td>Bilat III</td>
<td>Mega U</td>
<td>13</td>
</tr>
<tr>
<td>2</td>
<td>F</td>
<td>5.5</td>
<td>Bilat III/IV</td>
<td>Mega U</td>
<td>11</td>
</tr>
<tr>
<td>3</td>
<td>M</td>
<td>7.0</td>
<td>L III</td>
<td>UPJO</td>
<td>/</td>
</tr>
<tr>
<td>4</td>
<td>M</td>
<td>11.5</td>
<td>L III</td>
<td>Mega U</td>
<td>23</td>
</tr>
<tr>
<td>5</td>
<td>M</td>
<td>9.3</td>
<td>L IV</td>
<td>Mega U</td>
<td>19</td>
</tr>
<tr>
<td>6</td>
<td>M</td>
<td>6.3</td>
<td>Bilat I/III</td>
<td>Mega U</td>
<td>15</td>
</tr>
</tbody>
</table>

Table 2: Comparison of Patients who Developed UTI vs Those who did not, By Etiology

<table>
<thead>
<tr>
<th>Etiology</th>
<th>No UTI</th>
<th>%</th>
<th>UTI</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>UPJO</td>
<td>19</td>
<td>95</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Megaureter</td>
<td>12</td>
<td>71</td>
<td>5</td>
<td>29</td>
</tr>
</tbody>
</table>

Figure 2: Quarterly Frequency of Eligible and Enrolled Pts.

Protocol Compliance:
- Adherence to F/U Schedule:
  - 73/75 (97%) clinic F/U attended
  - 144/157 (92%) telephone F/U attended
  - 1/35 (3%) lost to F/U
- Medication Compliance:
  - 34/35 (97%) compliant with medication administration
  - 191/235 (81%) Med Logs completed and returned
- Median medication compliance = 100%

Conclusion

- Due to low prevalence of high grade AHN, multi-centre collaboration is critical to achieve recruitment targets.
- Feasibility results demonstrate high medication and follow-up compliance.
- This trial established a realistic recruitment rate for this population.
- A definitive trial on this topic is not only feasible but needed.

Future Direction

The ALPHA trial is now a definitive study and has opened a second site at the Hospital for Sick Children in June 2013, with the goal of recruiting 160 patients in total.

Funding Through Physician’s Services Incorporated
Clinical care dictates regular renal-bladder U/S be performed to determine if surgery is required and to manage the risk of urinary tract infections (UTI) in antenatal hydronephrosis (AHN) patients. The Society of Fetal Urology’s (SFU) grading system is used to classify severity of AHN, predict progression of condition, and influence treatment. Measurement of Antero-Posterior Diameter of the renal pelvis (APD) is observable by U/S and can also indicate severity of AHN.

**Background**

Clinical care dictates regular renal-bladder U/S be performed to determine if surgery is required and to manage the risk of urinary tract infections (UTI) in antenatal hydronephrosis (AHN) patients. The Society of Fetal Urology’s (SFU) grading system is used to classify severity of AHN, predict progression of condition, and influence treatment. Measurement of Antero-Posterior Diameter of the renal pelvis (APD) is observable by U/S and can also indicate severity of AHN.

**Objectives**

To examine how the SFU grading system and APD measurements compare in predicting the progression of AHN, risk of developing a UTI, and need for surgery.

**Methods**

**Study Design:**
- Randomized controlled trial, within the ALPHA pilot trial (HiREB #09-255)
- Prospectively followed for 12 months
- Renal-bladder US at baseline, 3, 6, 9, 12 months

**Eligibility Criteria:**
- Same as ALPHA pilot trial criteria

**Data Collection:**
- APD measurements and SFU grade of the most severe hydronephrotic kidney
- Frequency of UTI and Surgery

**Analysis:**
- APD and SFU Grade compared at baseline and F/U
- Student’s t-test compared means of APD and SFU grade of patients who develop UTI vs. no UTI and who had surgery vs. those who had no surgery

**Results**

**Progression of AHN:**
- Grade III patients’ APD decreased (Figure 1)
  - Of these, 7 (23%) improved to grade II or grade I (Figure 2)
- Grade IV patients’ APD did not change (Figure 1)
  - Of these, only 1 (17%) improved to grade II without surgery (Figure 2)

**Funding Through McMaster Surgical Associates**

- Most SFU grade IV patients do not show AHN improvement during the 1st year without surgery and bear a high risk of UTI (34%), especially when uncircumcised and have ureteric dilatation
- APD measurements seem to help identify patients at risk for UTI and surgery more accurately than the SFU grading system
- SFU grading system and APD measurements change differently over time thus both should be considered when managing AHN patients
Background

Continuous Antibiotic Prophylaxis (CAP) is a means to prevent fUTIs in infants with AHN. Empirically, CAP has been recommended for this population, but the existing evidence supporting this practice is relatively weak. There exists genuine uncertainty in the expert medical community due to a high degree of heterogeneity and inconsistent reporting of data surrounding this issue.

Objective

To evaluate the effect of important risk factors (including gender, VUR, circumcision status, CAP use, SFU grade) in the development of fUTIs in infants with AHN.

Methods

An AHN database of infants scheduled to undergo a VCUG was reviewed (2008-12)

Inclusion Criteria
• Patients between 0 – 24 months
• AHN on Ultrasound
• Had a VCUG

Exclusion Criteria
• Duplication Anomalies
• PUV
• Neurogenic Bladder

Primary outcome: fUTI
• Catheterized Specimen
• Temp > 38.1°C

5 a priori risk factors explored:
1. SFU AHN Grade [low(I-II) vs high(III-IV)]
2. CAP (Yes/No)
3. VUR (Present/Absent)
4. Gender
5. Circumcision Status

Results

Descriptive Statistics
• 376 patients analyzed
• 277 (74%) males
• 227 (60%) patients prescribed CAP
• 128 (34%) patients with High-grade AHN
• Of those 90 (71%) were prescribed CAP
• 79 (21%) patients had VUR
• Of those 76 (96%) were prescribed CAP
• Circumcision status available for 286 (97%)
• 76 (28%) of males were circumcised

Table 1: Univariate Analysis of Risk Factors

<table>
<thead>
<tr>
<th>Risk Factors</th>
<th>No. UTI (%)</th>
<th>Unadjusted OR (95% CI)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>AHN Grade</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>25 (19.5)</td>
<td>2.2 (1.2-3.9)</td>
<td>0.01</td>
</tr>
<tr>
<td>Low</td>
<td>25 (10.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AP</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>17 (11.4)</td>
<td>1.32 (0.7-2.5)</td>
<td>0.38</td>
</tr>
<tr>
<td>Yes</td>
<td>33 (14.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VUR Present</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>14 (17.7)</td>
<td>1.56 (0.8-3.1)</td>
<td>0.19</td>
</tr>
<tr>
<td>No</td>
<td>36 (12.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>15 (15.2)</td>
<td>1.1 (0.9-1.4)</td>
<td>0.53</td>
</tr>
<tr>
<td>Male</td>
<td>35 (12.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Circumcision (Males)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>31 (16.1)</td>
<td>2.7 (1.1-6.9)</td>
<td>0.02</td>
</tr>
<tr>
<td>Yes</td>
<td>4 (5.3)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 3: Post-hoc Analysis (N=131) of UTI Rate by Etiology

<table>
<thead>
<tr>
<th>Etiology</th>
<th>No. UTI (%)</th>
<th>OR (95% CI)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>UPJO - like</td>
<td>7 (7.3)</td>
<td>3.77 (1.3-11.3)</td>
<td>0.02</td>
</tr>
<tr>
<td>Megaureter</td>
<td>8 (23.0)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Results Continued

• Female fUTI rate was significantly higher than that of circumcised boys (p<0.01) (Table 1 and 2)
• To prevent 1 fUTI the NNT was 5 for uncircumcised males

Limitations

Missing Data
• Circumcision Status
• Etiology

High Rate of Co-intervention
• 96% in VUR group on CAP
• 71% in high-grade AHN group on CAP

Conclusion

• High-grade AHN and uncircumcised status are risk factors for fUTI after accounting for CAP and VUR.
• Female gender has the same risk of fUTI as uncircumcised boys.
• Megaureter is likely a separate risk factor.

Future Direction

A prospective (RCT) is needed to clearly define the role of each risk factor.

HiREB: 10-594-C