INCORPORATING PROSPECTIVE DATA COLLECTION INTO CLINICAL PRACTICE - THE HOLD EXPERIENCE

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• I do not intend to discuss an unapproved/ investigative use of a commercial product/device in my presentation.

• Information contained in this presentation is from previously presented/or published peer reviewed material.
• Background

• Rationale for the HOLD Project

• CIHR International Task Force

• Prospective Database (REDCap)

• Getting engaged
• Complication rates vary widely
• More than 300 surgical techniques reported
• Short to mid-term follow-up
• What matters for patients is still lacking
WHY A MULTICENTRE PROSPECTIVE HYPOSPADIAS DATABASE?
Different surgeons use different surgical techniques

Few studies address long-term outcomes

No standardized way of reporting pre- and post-operative results

Even the largest centers do not have enough numbers to answer the necessary questions.
RATIONALE FOR HOLD

• 3 P’s for improving practice and clinical outcomes
  • Prospective data collection – better quality of research
  • Periodic outcomes review – understand own and others’ results
  • Practice change – personal improvement – better outcomes – better patient care

(Snodgrass W, AUA Univeristy, www.auanet.org)
OBJECTIVES OF THE HOLD PROJECT

• What are the most common techniques?

• What is the true complication rate at an institutional, provincial and national level and what factors affect it?
  ▪ Preoperative hormone stimulation / Regional blocks
  ▪ Glans size
  ▪ Glans groove / Urethral plate
  ▪ Severity of VC
  ▪ Number of cases – (distal vs. proximal)

• How satisfied are adolescents with their hypospadias repair outcomes?
HOW IT ALL STARTED
International Pediatric Urology Task Force on Hypospadias

Standardizing Surgical Outcomes in Clinical Research

Date: September 18th to 19th, 2013
Location: Aria Hotel, Las Vegas, Nevada

Hosted by Dr. Luis Braga of McMaster University, in collaboration with the Hospital for Sick Children and Pediatric Urology researchers from across Canada, the USA, Brazil, France, Italy, and the United Kingdom.

Held immediately prior to the Pediatric Urology Fall Congress
MEETING OBJECTIVES

• Improve quality of reporting in hypospadias literature - a 20-item instrument adapted from STROBE.

• Create a Summary of Findings (SoF) table highlighting key points of studies.

• Set minimum standards for data collection through expert consensus.

• Create networks for future global/international cooperation in hypospadias research.
HOLD TASK FORCE
MEETING OUTCOMES

• Meeting Minutes circulated and posted as a white paper

• Consensus statement on data collection and reporting on hypospadias (in progress)

• Application of the STROBE statement to the hypospadias literature

Report on the International Pediatric Urology Task Force on Hypospadias

Braga LV, Children's Health, Hamilton, Ontario.

ABSTRACT

The conference was held September 19th, 2019 at the Fiat Hotel in Las Vegas, Nevada with the goal of developing evidence-based reporting standards on the hypospadias registry and developing a comprehensive, prospective registry on hypospadias and creating networks for future collaborative research in the field.

Introduction & Objectives

Pediatric surgeons from across Canada, the USA, Brazil, and Europe attended the conference. Participants included pediatric urologists, vasectomy researchers, and editors of various online and print journals. The conference was also attended by the hypospadias collaborative, which has traditionally provided guidance on the development of questionnaires on the patient's experience, staging criteria, and long-term outcomes.

MEETING OUTCOMES

• Meeting Minutes circulated and posted as a white paper

• Consensus statement on data collection and reporting on hypospadias (in progress)

• Application of the STROBE statement to the hypospadias literature
**Preoperative Assessment**

- Meatal location and/or level of division of corpus spongiosum, as defined by Figure 1
- Presence of associated genital anomalies
- Measured degree of penile torque
- Measured degree of ventral curvature
- Prior circumcision
- Use and details of preoperative hormone stimulation
- Details of any previous surgery for hypospadias

**Intraoperative Assessment**

- Fully-stretched dorsal penile length and diameter of the glans
- Depth of the groove separating the glans wings
- Length and width of the urethral plate (UP), extending from the ectopic ventral meatus to the tip of the glans
- Presence of hypoplastic urethra below the meatus, characterized by an absence of surrounding corpus spongiosum tissue
- Deficiency of the ventral skin
- Ventral curvature of the penis
- Elasticity or rigidity of the UP tissue
MINIMAL REPORTING ITEMS

**Surgical Technique**

- Anaesthesia and methods to achieve hemostasis
- **Severity and ventral curvature re-assessment after de-gloving**
- **Degree of ventral curvature and steps taken for correction**
- Type of surgical procedure performed, including any modifications
- Grafting use, including the donor site and its management
- Use of UP incision, including post-incision width
- Details of urethroplasty, including number of layers, suture size, suture type, and closure
- Glansplasty, if used, including suture size, type, and closure
- Barrier layers, if used, including number of layers and tissue used
- Additional procedures performed
- Skin closure, including suture size, type, and suture closure
- Urinary diversion and dressing
- Meatal position at the end of the procedure
- Foreskin management (preputioplasty or circumcision)
Follow-up and Outcome Assessment

- Age at follow-up
- Duration of follow-up
- Developmental milestones reached
- Presence of complications and their severity
- Assessment of voiding
- Cosmetic assessment
HYPOSPADIAS LONG - TERM OUTCOMES DATABASE (HOLD)
• Prospective data collection on all hypospadias surgeries from 2010 – present
  • Importance - consecutive cases

• Online database using REDCap to collect and store information
  • Infrastructure and Security to support multiple centres
WHY USE REDCap?

Research Electronic Data Capture (REDCap)

• Online tool to collect and manage data
• Accessible online (smartphones, tablets, etc)
• Intuitive, user friendly interface
• Customizable
• Free to add users and create projects
• Secure: designed to support HIPAA compliance

867 institutions in 71 countries
SECURITY

- Data stored on McMaster Server, encrypted and backed-up nightly.

- 256-bit encryption system designed to provide communication security over the internet.

- Audit trails track data manipulation and export by all users.
Longitudinal Data Entry

- Forms can be used once or multiple times per record
- Keeps study info organized by visit
- Complete forms - green, incomplete - red, and unverified - yellow

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REDCap has safeguards in place to prevent data loss while making changes to the database.

- During development, changes can be made in real time.
- After data collection begins, projects can still be safely updated.
- All updates during production are reviewed by an administrator.
• Policy for Data Access and Authorship (Data sharing agreement)
  • Same model as other registries
    • Hydronephrosis – (Tony Herndon)

• Research output - Presentations / Publications
  • CUA: 2013-19
  • ESPU: 2015, 2016, 2019
  • AUA: 2016, 2017, 2018, 2019
Cause and Effect versus Confounding—Is There a True Association between Caudal Blocks and Tubularized Incised Plate Repair Complications?

Luis H. Braga,* Kizanee Jegatheeswaran, Melissa McGrath, Bethany Easterbrook, Mandy Rickard, Jorge DeMaria and Armando J. Lorenzo
CURRENT DATABASE - DESCRIPTIVES

• 848 patients included in the database

• Location
  – Distal: 616 (72%)
  – Midshaft: 100 (13%)
  – Penoscrotal/perineal: 132 (15%)

• Median age at surgery: 16.9 mos.
CURRENT DATABASE DESCRIPTIVE

Complications

- Overall complication rate = 14.7%
- Fistula - 9%
- Glans dehiscence - 6%
CURRENT CENTRES

- McMaster University – Started 2010
- Children's Hospital of Eastern Ontario – February 2016
- Rhode Island Hospital – March 2015
- Hospital Geral Roberto Santos – Bahia Brazil - June 2015
Centres in Ethics Approval Process

- Dalhousie University, Nova Scotia, Canada
- Hamad Medical Corporation, Qatar
- All India Institute of Medical Services, India
BARRIERS

• There needs to be a research CULTURE shift

• Research happens all the time
  - Clinics, OR, meetings, rounds, etc

• It is part of what we do, how we grow !!!

• Research support – VERY IMPORTANT
  - if you don’t have it - volunteers
"START WHERE YOU ARE. USE WHAT YOU HAVE. DO WHAT YOU CAN."

- ARTHUR ASHE
GETTING INVOLVED
WHY SHOULD ONE GET INVOLVED?

• Clinical Benefits
  – Evidence-based improvement tool for your own practice
  – Establish minimal standards of care
  – Generalizability of published results

• Research Benefits
  – Publication of centre specific data
  – Collaboration in multi-centre projects
  – Professional recognition (Merit)
  – Evidence-based research - higher quality (in the absence of RCTs)
GETTING STARTED

Do not wait until the conditions are perfect to begin. Beginning makes the conditions perfect.

Alan Cohen
IN THE END

Our legacy

• We own to the new generation of pediatric urologists and to our patients to try to do better
THANK YOU!

If you are interested in getting started with your own databases, please contact Melissa McGrath (mcgram2@mcmaster.ca)