Introduction

Modern staged repair has dramatically improved outcomes for children with bladder exstrophy (BE). However bladder neck reconstruction (BNR) success remains only 70%. Lack of an evidence-based surgical decision making tool reduces the ability to predict and mitigate surgical failure risk.

Objectives

We sought to examine how surgical decision making tools and algorithms are created and what means would lead to the most accurate and clinically useful tool for the bladder exstrophy care team.

Methods

A search of evidence was undertaken and included databases PubMed, EMBASE and CINAHL. Search terms included bladder exstrophy, plastic surgery, bladder, urethra, and bladder neck surgery. Boolean operators were used as appropriate and also included phrase and proximity searches as well as incorporating truncation. Lack of evidence led to second search focused on algorithms and included the terms expert, decision, utility, efficiency, and validation studies. A third search targeted algorithm

high-specialties oncology and cardiology added terms as such, neoplasms, cardiac surgical procedures, medical oncology, development and create.

Retrospective chart review included 100% capture of all pediatric patients who underwent BNR at JHH between May 2006 and August 2012, n=38. Chart review examined presurgical data points such as age at time of BNR, pre surgical bladder size, pre surgical voiding residual volume, presurgical pelvic floor strength and relaxation, hx of fistula, and hx of bladder stones. Also examined were post BNR outcomes such as level of continence, fistula formation, incidence of UTI, and bladder or kidney stone formation post surgery.

Review and Grading of Evidence

Evidence was reviewed and graded on criteria including rigor, replicability, generalizability and sample size, as well as complexity and appropriateness of statistical analysis. The search yielded no RCTs or Level I evidence. Included were two Level II quasi-experimental articles, one each A and B articles. Level III, non-experimental articles totaled ten with seven A quality and three B quality. While no Level IV articles were included, three Level V articles were identified. Level V articles included one A quality and two B quality. Additionally, evidence was sorted and ranked by their value, as it pertained to the practice problem.

Summary of Evidence

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<th>Level</th>
<th>Total #</th>
<th>A quality</th>
<th>B quality</th>
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<td>V</td>
<td>3</td>
<td>one</td>
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Synthesis of the Evidence

The evidence overwhelmingly favored retrospective chart review and exhaustive data mining (DM). The evidence further pointed to rigorous statistical analysis. Included in the evidence were multivariate linear regression, Fisher’s exact test, Wilcoxon rank sum, Mann-Whitney U test multiple methods. Classification and Regression Tree (CART) analysis specifically was a binary recursive partitioning method. Classification and Regression Tree (CART) analysis' non-parametric approach allows appropriate and accurate analysis of variables that are not evenly distributed. Further, CART analysis allows the accurate management of a large number of variables in building an algorithmic model.

Outcome Data Analysis

Pearson’s Chi Square and Odd Ratios were run to determine independent variables of greatest significance. Once variables of greatest importance were identified, 31 Classification and Regression Tree (CART) Analysis were run. Valuable data extracted included the fact that 75% of all patients with a presurgical hx of UTI’s required post BNR catheterization. Further, 100% of patients in the sample who had a hx of failed primary bladder closure, (n=5), required post BNR augmentation cystoplasty. Only 10% of patients with a presurgical history of unmanaged constipation were able to achieve night time continence post BNR, while 56% of patients whose constipation was well managed before BNR surgery were able to achieve night time continence post BNR. Finally, only 33% of patients with a negative hx of failed primary closure suffered from post BNR bladder stones, while 80% of patients with a positive hx of failed primary closure suffered from post BNR bladder stones.

Project Outcomes and Next Steps

CART outcome data will be transformed into a surgical decision making algorithm through the assembly of an interdisciplinary panel of bladder exstrophy experts in Autumn 2014. Experts will collaboratively evaluate CART data, build a surgical decision making algorithm. Finally, the decision making algorithm will be disseminated worldwide to the bladder exstrophy community so that other institutions, providers, and ultimately patients, may benefit from an evidence-based approach to surgical candidate selection.

Evidence-based decision making is critical to ensuring a strong, scientific approach to clinical problems. Thus far it has been difficult to develop evidence based tools for surgical decision making in BE due to the fact that there are no large BE cohorts who have undergone comprehensive presurgical evaluation. By obtaining 100% capture of BE patients who have undergone comprehensive presurgical evaluation, this project is the first step in identifying and illustrating meaningful pre/post surgical relationships. This is a critical step in improving surgical candidate selection and thus surgical outcomes.