



Cumulative summation (CUSUM) charts in the monitoring of hypospadias outcomes: A tool for quality improvement initiative



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KEYWORDS

Hypospadias; Complications; CUSUM; Cumulative summation; Hypospadias repair **Abstract** *Objective*: Cumulative summation (CUSUM) charting is a statistical tool that allows an individual surgeon or surgical department to monitor any binary outcome and rapidly detect when complications are outside the acceptable limits. We applied CUSUM statistical analysis to hypospadias repair to utilize the results in our own quality Improvement process.

Materials and methods: An institutional review board-approved retrospective review of all patients who underwent hypospadias repair by a single fellowship trained pediatric urologist at a single institution between September 2004 to July 2009 was performed. To graphically represent the complication rates and to assess for unacceptable rates, the use of CUSUM control charting was employed.

Results: In our retrospective review, there were a total of 184 patients who underwent a total of 203 surgeries. Using CUSUM analysis, our incidence of major complications was within acceptable limits until approximately the first 150 operations had been performed, at which time the complication rate fell below the lower limit, indicating performance exceeded expectations.

Conclusion: CUSUM statistical charting was successfully applied to the retrospective monitoring of hypospadias outcomes at our institution. This is the first known publication in which CUSUM charts were used to evaluate complications of hypospadias repair.

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Introduction

Hypospadias is one of the most common congenital malformations of the genitourinary system, present in 1/250 [1] live

male births. It is an anomaly of the penis in which the urethral meatus opens along the ventral aspect of the penis and is often associated with chordee and a dorsal hood of foreskin. A variety of operations and techniques is described to repair

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this malformation. Hypospadias repair is associated with a number of major and minor complications, including bleeding, meatal stenosis, urethrocutaneous fistula, urethral diverticulum, urethral stricture, and persistent penile curvature [2]. When considering the technically challenging nature and the various options for repair, the need to formally monitor surgical outcomes is of great importance.

In recent years, outcomes research has gained popularity, and there are many publications dedicated to outcomes with respect to hypospadias repair. Hypospadias surgery is performed by pediatric urologists with variable training and experience levels. Outcomes in the literature may be very different from individual outcomes, thus highlighting the need for an efficient, prospective method of monitoring individual outcomes. Also, many patients and families are aware of differences in surgeon outcomes, and they commonly request surgeon-specific data. Additionally, alerts should be in place if outcomes are outside the realm of a generally accepted complication rate.

Cumulative summation (CUSUM) charting is a statistical tool that allows an individual surgeon or surgical department to monitor the binary outcomes of the absence or presence of a particular complication. Thus, one can rapidly detect when complications are outside the acceptable limits. CUSUM analysis was first introduced by Page in 1954 [3]; it is a statistical and graphical tool that examines trends for sequential events over time. It can be utilized in a variety of applications, and was first applied to surgical outcomes in 1994 [4]. In graph format, CUSUM charts can represent the outcomes of a surgeon's case series. Using the surgeon's complication rate and an acceptable complication rate, the graphs can easily represent if and when an unacceptable complication rate is reached. This allows surgeons to monitor outcomes in a more prospective fashion [5].

Chalasani et al. [6] recently applied this analysis to complications related to radical cystectomy. This tool has not previously been applied to pediatric urology. As hypospadias repair is a complicated operation, with a variety of techniques, CUSUM analysis could be potentially useful in this realm. We applied CUSUM statistical analysis to hypospadias repair to utilize the results in our own quality improvement process.

Materials and methods

An institutional review board-approved (# 2009-0276) retrospective review of all patients who underwent hypospadias repair by a single fellowship trained pediatric urologist at a single institution between September 2004 to July 2009 was performed. Surgery date, age at surgery, preoperative diagnosis, type of surgery, complications, and length of follow up were analyzed. Data were further subdivided by repair type (primary vs. staged vs. secondary), and hypospadias type. Hypospadias type was divided into distal (glandular, coronal, and distal) and proximal (midshaft, proximal, scrotal, and perineal). Types of repair included MAGPI, TIP, staged proximal repair, and repair of hypospadias complications. Complications included urethrocutaneous fistula (UCF), glans dehiscence, meatal stenosis, urethral diverticulum, and reoperation for any

reason. These complications were then analyzed utilizing the CUSUM approach.

We established an accepted complication rate by performing a comprehensive literature review on hypospadias complications. We performed an OVID search with the key words "hypospadias", "repairs", and "complications". Using data obtained from 11 related studies [7-17] on hypospadias repair outcomes, a weighted average of the complication rate from the 11 studies was obtained (number of complications divided by number of patients). This served as the guideline for boundaries of acceptable complication rates. The articles were further analyzed by complication rate, and the lowest reported rate was used for the lower limit and the highest reported rate was used for the upper limit. For all patients collectively, we assigned the unacceptable complication rate at 20% — a number that is based on expert opinion and our review of the literature. We assigned a low-end threshold at 2%, which was based on the lowest complication rate reported in the literature. The determined range for UCF was 2-10% for distal repairs, 5-20% for proximal repairs, and 10-30% for revisions. The determined ranges for dehiscence, meatal stenosis, and diverticulum were 3–10%, 3–10%, and 5–20%, respectively. These upper and lower limits were then used as the boundaries for our own constructed CUSUM charts.

To graphically represent the complication rates and to assess for unacceptable rates, the use of CUSUM control charting was employed [3,17]. CUSUM charts are a cumulative measure of performance over time with boundaries indicating the threshold of acceptability. The threshold of acceptability is defined by the acceptable complication rate, unacceptable failure rate, and type I and type II errors. Type I errors are used to minimize detection of an increased complication rate when it has not occurred (false-positive). Type II errors are used to minimize failure of detection of an increased complication rate that has occurred (false-negative). In our analysis, the error rates were set at 10%. As noted by Rogers et al. [18], 10% is a commonly-used value for error rates. They note that "the choice of values for α and β , the false-positive and false-negative rates, as well as those for p0 and p1 (or, equivalently, the odds ratio), are not always immediately obvious and depend on the setting and specific application" [18]. The other specified values were set for each type of complication, as described previously. CUSUM charts were constructed for any major complications in any hypospadias repair. CUSUM charts were also constructed for meatal stenosis, dehiscence, diverticulum, and UCF stratified by distal hypospadias repairs, proximal hypospadias repairs, and revisions. The calculated boundaries allow for the sequential monitoring of the complication rates so that a rate that crosses the boundary can be detected. If the cumulative rate crossed the upper boundary, then we concluded that the complication rate increased to the unacceptable region. Similarly, if the cumulative rate crossed the lower boundary, we concluded that our complication rate is less than or equal to the acceptable complication rate.

Results

The weighted average of complication rates based on number of patients from the literature review of the 11

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