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Am I out of control? The application of statistical process control charts to children's surgery

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ABSTRACT

Aims: To illustrate the construction of statistical control charts and show their potential application to analysis of outcomes in children's surgery.
Patients and methods: Two datasets recording outcomes following esophageal atresia repair and intestinal resection for Crohn's disease maintained by the author were used to construct four types of charts. The effects of altering the target signal, the alarm signal and the limits are illustrated. The dilemmas in choice of target rate are described. Simulated data illustrate the advantages over hypothesis testing.
Results: The charts show the author's institutional leak rate for esophageal atresia repair may be within acceptable limits, but that this is dependent on the target set. The desirable target is contentious. The leak rate for anastomoses following intestinal resection for Crohn's disease leak is also within acceptable limits when compared to published experience, but may be deteriorating. The charts are able to detect deteriorating levels of performance well before hypothesis testing would suggest a systematic problem with outcomes.
Conclusions: Statistical process control charts can provide surgeons with early warning of systematic poor performance. They are robust to volume–outcome influences, since the outcome is tested sequentially after each procedure or patient. They have application in a specialty with low frequencies of operations such as children's surgery.
Type of study: Diagnostic test.
Level of evidence: Level II.

The analysis of surgical outcomes has traditionally been viewed as a comparison of proportions, which can then be subjected to formal statistical hypothesis testing. For example a surgeon or institution may have a proportion of patients survive, or a proportion of patients suffer a complication after a specific procedure. This proportion is compared to published outcomes and the surgeon, or institution is deemed to be within acceptable limits of performance if statistical comparison of the mean lies within a margin of the published standard. However, this approach may lead to poor discrimination of surgical performance where either the surgeon's performance changes [1], or the condition is seen with low frequency, as often occurs in children's surgery.

The methods for analyzing a process where the sample size is not predetermined were discovered independently in the 1940s by Abraham Wald in New York and GA Barnard in England [2,3]. Their initial application was to improve industrial processes in war production. However, their utility in analysis of medical processes was recognized [4–6], and in particular their application to outcomes in cardiac surgery accepted [7,8]. The charts will demonstrate surgical outcomes as being out of control for any reason, not simply the surgeon's performance. Wald's original monograph on the subject was titled “Sequential analysis” [9], and the graphical outcome of this approach represents an example of a statistical process control chart.

There are few reports of the use of statistical process control charts relating to children's surgery [10–12]. There may be confusion with funnel charts, which have different applications in comparison of institutional performance [13]. Statistical process control charts represent a graphical depiction of sequential analysis in which the outcome is assessed after each further procedure with the process being designated as either in control or not; they are specifically designed to detect deterioration in performance earlier than hypothesis testing. Funnel plots relate the mean outcome of either institutions or individuals to confidence intervals based on the sample size; they are not designed to detect a deterioration in performance. Conventional hypothesis testing detects significant differences in samples based on

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probability distributions; again it is not designed for early detection of deterioration in small samples.

The variety of different charts and the processes for risk stratification will consequently be unfamiliar to most pediatric surgeons. The aims of this study are firstly to demonstrate the application of the various charts using outcomes data from esophageal atresia repair, and intestinal resection for Crohn's disease. Secondly, the utility of this approach – and potential barriers – to monitoring of surgical performance within children's surgery is discussed.

1. Patients and methods

Two clinical datasets maintained by the author were utilized to illustrate the charts. The first dataset recorded the outcomes of esophageal atresia surgery, and the second the outcomes of intestinal resection for pediatric Crohn's disease. In addition, a simulated dataset of two surgeons with contrasting mortality rates was constructed to compare the use of hypothesis testing techniques with process control charts.

All babies undergoing surgery for esophageal atresia for the last two decades in the author's institution are recorded in a customized database (Access, Microsoft). The outcomes of interest for this study were anastomotic leak and mortality. Other variables recorded included the presence of cardiac and renal anomalies, which were used to allow risk stratification.

The author's personal series of intestinal resections for Crohn's disease for two decades was also so recorded. The outcome of interest for this study was anastomotic leak or other septic complication.

For both datasets the outcome is recorded as a dichotomy in chronological order. Use of the NHS online tool determined this study did not require ethical approval.

1.1. Statistical process control charts

To construct the charts, the following components are required [8,14,15].

a) The charts all utilize a series of outcomes in chronological order. The patient outcomes are dichotomous, with failures, either leaks or deaths, coded as 1, and successes, no leak, or survival, coded as 0. This is the only patient variable. It is possible to construct charts using continuous rather than discrete data, but this is beyond the scope of this study. We shall call this outcome X_i for the i^{th} outcome
b) For each outcome, a target, or desirable proportion of outcome is set. We shall call this θ_0. For our example charts, we set this result from a review of published outcomes for the two conditions.
c) For each chart, an unacceptable rate is chosen. This is termed the signal level. We shall call this θ_1. This is set according to the importance of the outcome, but empirically we would suggest the chart signals when the failure rate increases by half. So if the acceptable rate is 5%, the chart signals at 7.5%. The desired signal level is however entirely at the discretion of the observer, but should be a level at which some remedial action will be triggered.
d) The desired levels of a type 1 error (α) and a type 2 error (β). These are set according the clinical importance of either not incorrectly assigning a surgical process as out of control versus the importance of not allowing an out of control process to continue. For example, if the outcome for the patient was critical, we might wish to set α to a relatively high level, say 0.2. This would mean we had a 20% chance of incorrectly stating the process was out of control, because we do not want to run the risk of allowing patients to come to serious harm by allowing a surgical process to continue when there is a systematic problem. Alternatively, if the clinical outcome was of little importance to the patient, but mattered a great deal to the surgeon, then we might set β to a relatively high level, again say 0.2. We would then be stating that we accept a 20% chance of allowing a defective process to continue. The usual limits are 0.05, but the values chosen are a judgment that must be explicitly chosen according to the process under examination. There is no need for α to equal β.
e) The slope of the event line. This varies with the type of graph chosen, and is described below.
f) The acceptable limits of the process. We shall call these l_1 for the upper limit and l_0 for the lower limit. Their construction is described for each chart in the following section.

Four different types of chart are described: a) unadjusted cumulative sum (CUSUM) chart, b) unadjusted sequential probability ratio test (SPRT) chart, c) Observed–expected CUSUM chart, d) risk-adjusted SPRT chart. A fifth type, the two-sided risk adjusted CUSUM chart [16], is omitted in the interests of brevity.

All were constructed using Excel spreadsheets (Microsoft). Although statistical process control charts in manufacturing processes would typically use a sample of the product to be analyzed, in surgical applications, it is logical to use each procedure, or patient, as a separate item of interest.

1. Unadjusted cumulative sum (CUSUM) chart [17].
   This chart utilizes the procedure number as the abscissa. The ordinate is the sum of the failures, recalculated after every patient, or procedure, when a failure is coded as 1 and a success as 0. It is constructed as follows:
   a) Let $i =$ each consecutive procedure, or patient, then $Y_i = Y_i + Y(_{i-1})$, where $Y_i = 0$ for a success and 1 for a failure.
      The limits of the chart are upward sloping lines given by the following equations. It is interesting to note that none of these variables are dependent on the patient data and can be predrawn.
   b) Lower limit, $l_0 = i \times s - h_0$. A lower limit of zero is applied for this limit.
   c) Upper limit $l1 = i \times s + h_1$
   d) $s = \ln((1-\theta_0)/(1-\theta_1))/\ln(\text{OR})$
   e) Natural logarithm of odds ratio $(\ln \text{OR}) = \ln(\theta_1(1-\theta_0)/(\theta_0(1-\theta_1))$
   f) $h_0 = \ln((1-\alpha)/\beta)/\ln(\text{OR})$
   g) $h_1 = \ln(1-\beta)/\alpha))/\ln(\text{OR})$
2. Unadjusted sequential probability ratio test (SPRT) chart.
   In this chart the abscissa is again the procedure number. As with the CUSUM, each patient or procedure is coded as 1 for a failure and zero for a success and the ordinate is then defined as follows:
   $Y_i = Y(_{i-1}) + (X_i - s)$. This is the log likelihood ratio.

The control limits are horizontal lines given by equations f) and g) above.
Unlike the CUSUM chart, this chart does not trend upwards. An in control process will oscillate around zero, while an out of control process will breech the upper limit. A process which is improving will produce a downward line, eventually breeching the lower limit.

3. Observed–expected CUSUM.
The chart should increase if the process is deteriorating and decrease if there is improvement. A process in control should oscillate around zero. For example, if the expected failure rate is 10% the target would be the observed failures minus 10 after 100 procedures.
Again, the abscissa is the procedure number and the ordinate is given by:
$Y_i = Y_{(i-1)} - p_0$ for a success and $Y_i = Y_{(i-1)} + 1 - p_o$ for a failure. The control limits are h_0 and $h_0 \times -1$.
4. Risk-adjusted SPRT
The ordinate is given by $Y_i = Y_{(i-1)} + (1 - s_i)$ for a failure and $Y_i = Y_{(i-1)} - s_i$ for a success. The chart is designed to adjust for the patient, or procedure, specific risk for each case.
We have previously published a study of statistical modeling of survival of babies born with esophageal atresia, in which survival was almost completely explained using a model consisting of major congenital cardiac defects and severe renal anomalies as covariates [18]. We utilized the coefficients from the logistic regression model of that study to calculate patient specific probability of survival for the risk adjusted models.
From our previous work we modeled survival as the following equation:
Logit probability of survival = 4.01 − (4 × presence of severe renal anomaly) − (3.26 × presence of major cardiac anomaly).
Therefore:

$$\text{Probability of survival} := \frac{\exp(4.01 - (4 \times \text{presence of severe renal anomaly}) - (3.26 \times \text{presence of major cardiac anomaly})}{1 + \exp(4.01 - (4 \times \text{presence of severe renal anomaly}) - (3.26 \times \text{presence of major cardiac anomaly}))}.$$

$$\text{Probability of death} = (1 - \text{probability of survival})$$

$$\text{Adjusted}p_{a0} = \text{probability of death}$$

$$\text{Adjusted}p_{a1} = p1 + \text{probability of death}$$

$$\text{Adjusted odd ratio} = \ln\frac{p_{a0}(1 - P_{a1})}{p_{a1}(1 - P_{a0})}$$

$Y_i = Y_{(i-1)} + Y_i - s$, where $Y_i = 1$ for a failure and 0 for a success.
s is as per equation (d) in methods.

2. Comparison with hypothesis testing techniques

For the purpose of comparing statistical control charts with conventional hypothesis testing, simulated mortality outcomes for two surgeons, A and B, were created. Surgeon A has a mortality rate of 10% while surgeon B has a mortality rate of 20%. The sequence order of the adverse event was generated randomly using the Excel function RANDBETWEEN( ). Empirically, we believe that a doubling of mortality rate would be a cause of concern. We then modeled the effect of sample size by performing Fisher's exact test on these two rates with increasing samples. We used the same data to draw CUSUM charts, stopping when the sample size gave a signal.

3. Results

3.1. Illustration of chart construction using anastomotic leaks following intestinal resection for Crohn's disease

107 consecutive children were personally operated on by the author for Crohn's disease with performance of an intestinal resection with an anastomosis. There were 13 leaks for a leak rate of 12%.

Literature review identified eight publications where the leak rate following intestinal resection for Crohn's disease could be identified [19–26]. These are shown in Fig. 1 with the author's series. Excluding the author's series, this suggested the target rate for a septic complication following resection and anastomosis for Crohn's disease should be 10%.

The target rate for septic complications following intestinal resection for Crohn's disease was therefore set at 10%. Empirically, the signal rate was then set at 15%. The resulting SPRT, Observed–expected and CUSUM charts are shown in Fig. 2. For all charts α and β were set at 0.05.

3.2. The effects of altering the target rate, the signal rate, α and β

Using the same series of outcomes for resections for Crohn's disease, the effects of altering the chart settings are illustrated using a CUSUM chart in Fig. 3. From top left, the first chart shows the settings of a target leak rate of 10% with a signal rate set at 15%,

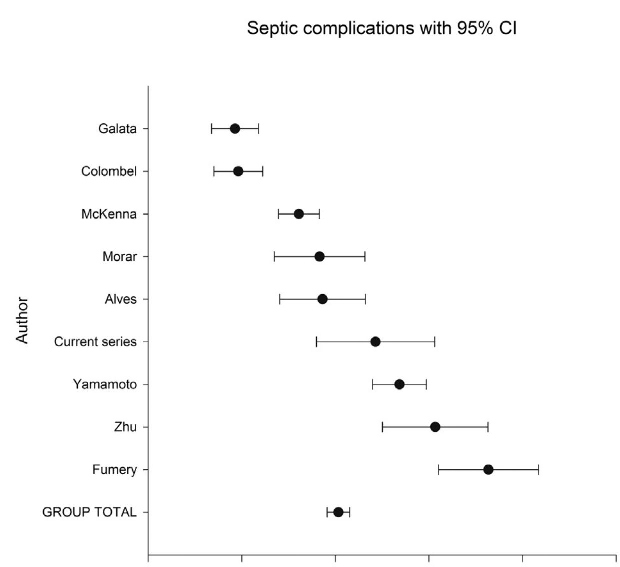

Fig. 1. The incidence of anastomotic leak or other septic complication following intestinal resection for Crohn's disease from published literature.

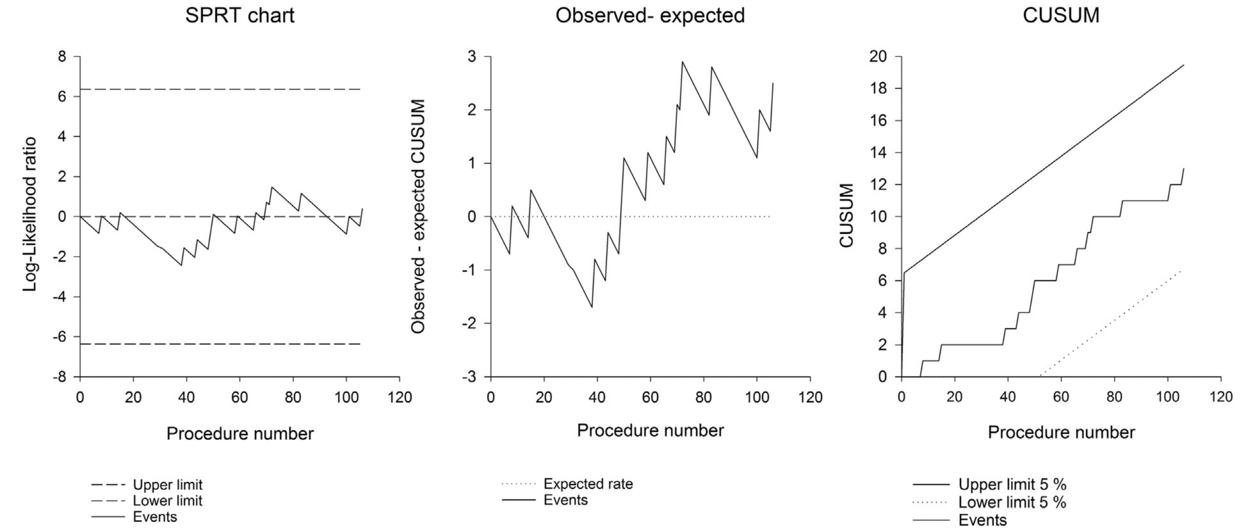

Fig. 2. Sequential probability ratio test (SPRT), Observed–expected and cumulative sum (CUSUM) charts showing leaks from Crohn's anastomoses. Same date all charts.

with α and β both set at 5%. Top middle shows the effect of setting the target rate to 5%, with a signal rate at 10%, α 20% and β 20%: the chart shows the process is out of control after patient 51. Top right shows a target rate of 10%, signal rate of 15% with α and β both set at 20%; notice how the limits are closer to the event line than in top row left.

Bottom row left has target rate set to 20% and signal rate to 30% setting α and β to 20%. Making these target and signal rate more lenient has the effect of the process crossing the lower limit line, indicative of a process which might be improving; we might consider re-setting the graph to zero in this situation. Bottom right shows the converse of setting α and β to more liberal limits of 40%; the target lines become

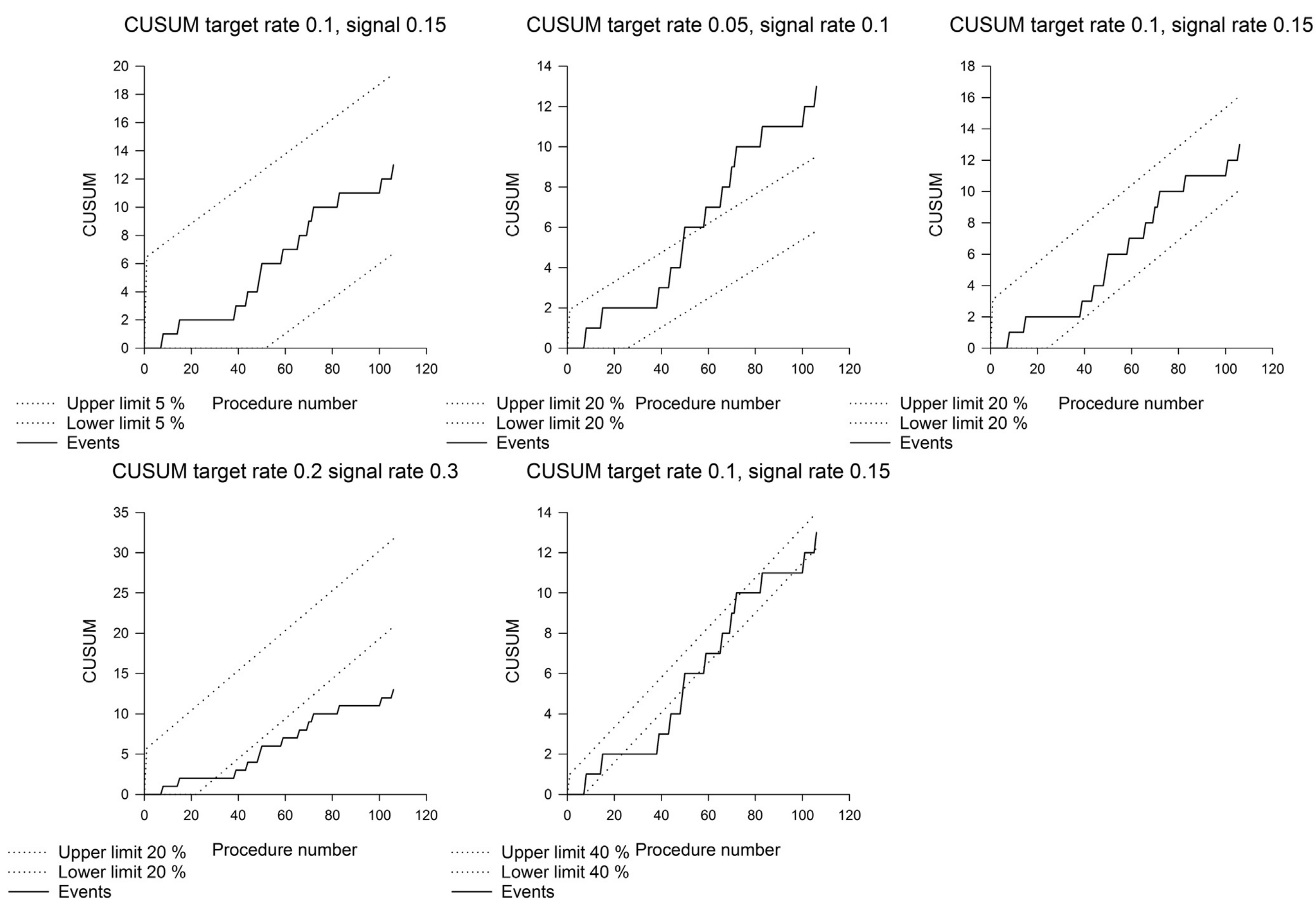

Fig. 3. The effects of altering the target rate, the signal rate, α and β. Same patient data for Crohn's anastomotic leak in all charts.

much closer to the event line. Essentially this is stating we are more prepared to accept either a type 1 or a type 2 error. We might wish to do this if the consequences of failing to signal were particularly clinically important.

3.3. Illustration of difficulties in choosing a target level using anastomotic leak for esophageal atresia

23 of 172 esophageal atresia repairs in the author's institution suffered an anastomotic leak (13%). The outcome of a UK national audit of esophageal atresia surgery had suggested the average national anastomotic leak rate to be 5.4% [27]. A series of nine publications where the anastomotic leak rate for esophageal atresia repair was identified [27–35], giving a total of 1576 esophageal atresia repairs with 228 leaks. This suggested a target leak rate of 14% (95% CI 12–16). The effects of contrasting these two target rates are illustrated in Fig. 4. The varying leak rates of the different reports are illustrated by use of a funnel plot, Fig. 5.

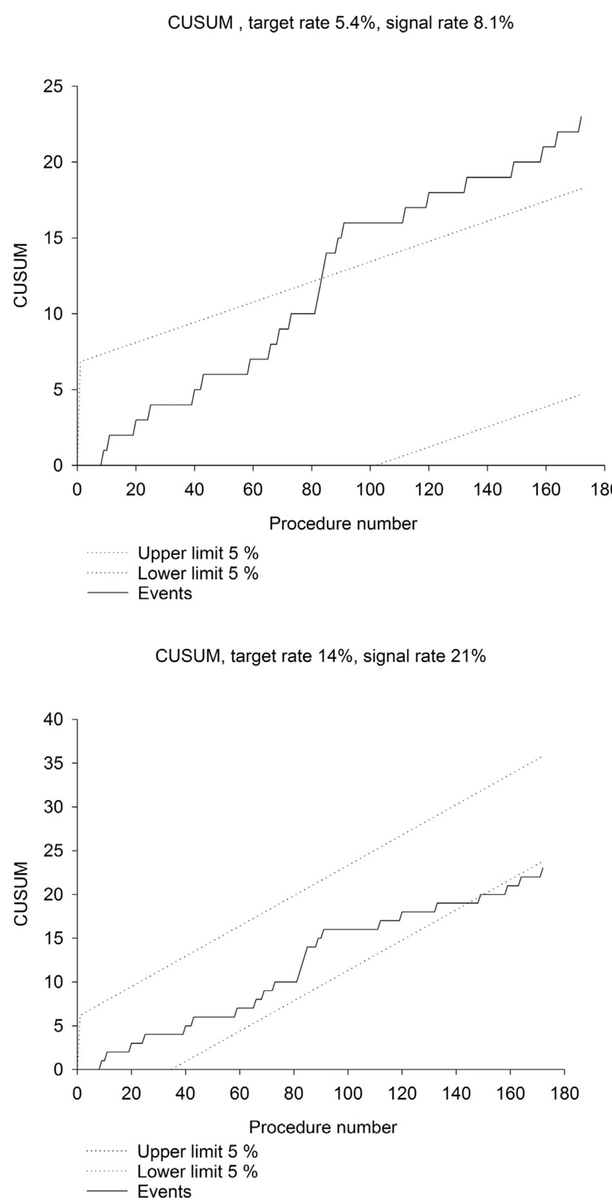

Fig. 4. Contrasting target and signal rates for esophageal atresia anastomotic leak rates.

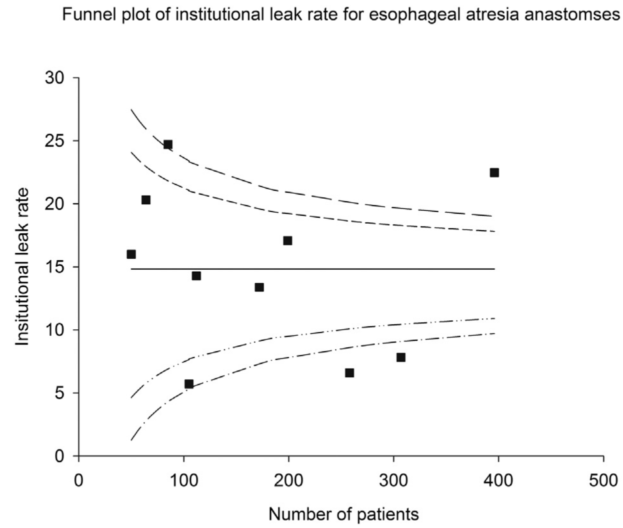

Fig. 5. Funnel plot of institutional leak rate for esophageal atresia leak rates with sample size.

3.4. Calculation of patient specific risks using mortality following esophageal atresia surgery as an example

Our previous work analyzing survival among babies born with esophageal atresia involved the construction of a logistic regression model [18]. This gave survival probabilities of 0.98 where there were neither severe renal nor major cardiac anomalies, 0.67 in the presence of a major cardiac anomaly, 0.5 in the presence of a severe renal anomaly and 0.03 when there were both severe renal and major cardiac anomalies. This is in accord with the Kaplan–Meier graphs of survival for the dataset. Sequential probability ratio charts for unadjusted and risk adjusted survival are shown in Fig. 6.

3.5. Comparison with hypothesis testing

The comparison of two surgeon's simulated outcomes of 10% and 20% mortality using Fisher's exact test with increasing sample size is tabulated in Table 1. The difference between the two rates becomes statistically significant after patient 111, requiring a sample size of 222.

CUSUM charts with a target rate of 10% and a signal rate of 20% with increasing sample sizes are shown in Fig. 7. The chart signals when the total sample size is 40. There is an obvious advantage over the hypothesis testing technique in the early detection of a systematic difference.

4. Discussion

All surgeons should be curious as to whether their outcomes are within acceptable limits. However, deciding what those limits should be is more complex than at first appears. The aim of this study is to highlight a means for surgeons to track their outcomes using a graphical method which is easy to understand, and which offers objective, quantifiable analysis with the ability to detect small changes earlier than conventional statistical hypothesis testing. It is accepted that the sequential probability ratio test offers the most efficient technique for the early detection of a process which is out of control. While other techniques are available [36], the charts have the advantage of being easily comprehended without the need for complex statistical knowledge.

While there are well established national programs to improve surgical outcomes, such as the national surgical quality improvement program [37,38], and local initiatives such as morbidity and mortality meeting, there are limitations to these approaches. In the case of the

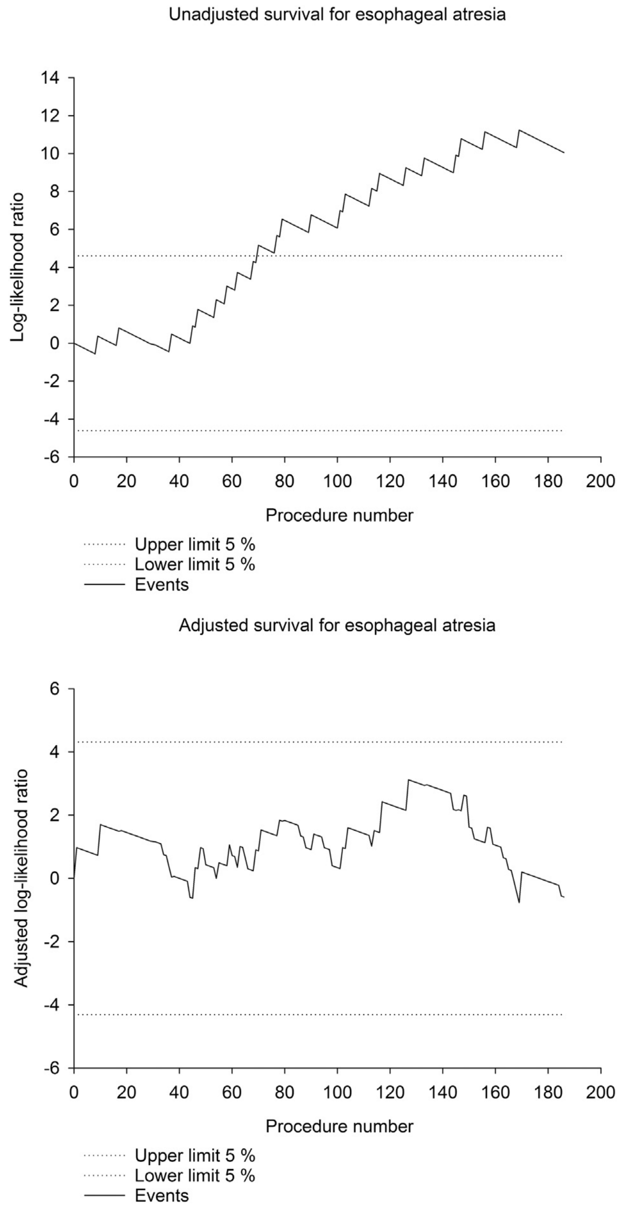

Fig. 6. Unadjusted and risk adjusted SPRT charts for survival of babies with esophageal atresia.

former, low volume specialties such as pediatric surgery will produce outcome indices with wide confidence intervals, leading to perhaps false reassurance regarding performance. Indeed this limitation was commented on in the pediatric iteration of the program [39]. Subsequent publications show the utility of this approach [40]. Local morbidity meetings, while providing a rapid and in-depth discussion of adverse outcomes, seldom have reliable objective analysis of numerical comparisons. The integration of statistical control charts to such meetings has an obvious application.

Table 1
Comparison of proportions using Fisher's exact test. Effect of increasing sample size on probability testing.

Sample size	Surgeon A or B	Comparison of c. 10% vs 20%	p
20	10	1 vs 2	1
40	20	2 vs 4	0.61
80	40	4 vs 8	0.34
160	80	8 vs 16	0.12
200	100	10 vs 20	0.07
222	111	11 vs 22	0.058
224	112	12 vs 24	0.04
320	160	16 vs 32	0.01

The limitations of traditional hypothesis testing are the inability of the test to identify small changes in small samples, and the problems with repeated testing, which will lead to false positive outcomes. This study was prompted by one of the author's series of intestinal anastomosis for Crohn's disease suffering an anastomotic leak. Simple calculation of the leak rate and comparison with published outcomes showed some series where the leak rate was higher and some where the leak rate was lower than the author's rate. Calculating confidence intervals still did not answer the question of whether there was a systematic problem, or there was a deterioration, in the author's results. The application of sequential analysis techniques allows objective, quantifiable robust monitoring of surgical outcomes, with early detection of deterioration. In this case, it appears that the anastomotic leak did not signify an underlying systemic problem, although the observed–expected chart might suggest a deterioration.

Which chart should be utilized? Clearly, if there are variables with major effects on the outcome of interest, some form of risk adjustment is mandatory. Otherwise, the choice of CUSUM, SPRT or Observed–Expected chart lies in individual preference. The observed–expected chart seems to the author the most intuitive to understand.

The simulated data of two surgeons with mortality rates of 10% and 20% illustrate the strengths of sequential analysis compared to hypothesis testing. The charts signal after patient 40 when there is no statistically significant difference between the two groups until after 220 patients.

The problem of the setting of the appropriate target rates for the control charts is illustrated by the charts using the leak rate for esophageal atresia surgery. If the leak rate of 5.4% suggested by the UK national study was adopted as our target rate [27], then our esophageal atresia leak rate was unacceptable after patient 81 in the series of 172 children. However if we adopted the target rate of 14% calculated from a group of 9 publications, then our practice is acceptable, and indeed might be improving. Clearly both conclusions cannot be correct, and this illustrates the dilemma of the charts. Reports of the use of control charts where the target rate are based on a single published standard are susceptible to this bias [11,12]. The original descriptions of the chart's use also fail to offer standard techniques for deciding on the appropriate target and signal rates [7,14]. One approach might be to calculate a trimmed average, excluding the studies with results beyond the interquartile range. Indeed the funnel chart illustrating the variation in the reported institutional leak rates supports this approach, with the best and worst performers being outliers beyond the 99% CI. Use of the interquartile range for the nine publications would have led to a target rate of 13% for leak after esophageal atresia surgery.

Given that it is possible to construct the charts with a target and signal rate which will reassure the surgeon incorrectly, who then should set the target and signal limits for process control charts? There is a balance in setting a rate which aims to improve standards, and one which is unattainable for most surgeons. While we should not aim for mediocrity, neither should we discriminate against standard practice. It should be noted that the charts neither support nor refute a volume–outcome relationship. Out of control processes in high volume surgeons or centers would be as likely to be detected as low volume surgeons or centers.

If the process crosses the lower limit, consideration should be given to resetting the chart to zero. Surgeons may well ask why, if they are performing well, the chart should be reset. The reason is that we are attempting early detection of a change in performance. If the event line is well below the lower limit, it will take longer to signal if there is a deterioration. In plain terms, a surgeon who was excellent two years ago may now be underperforming. We should not allow previous outcomes to detract from the analysis of current performance.

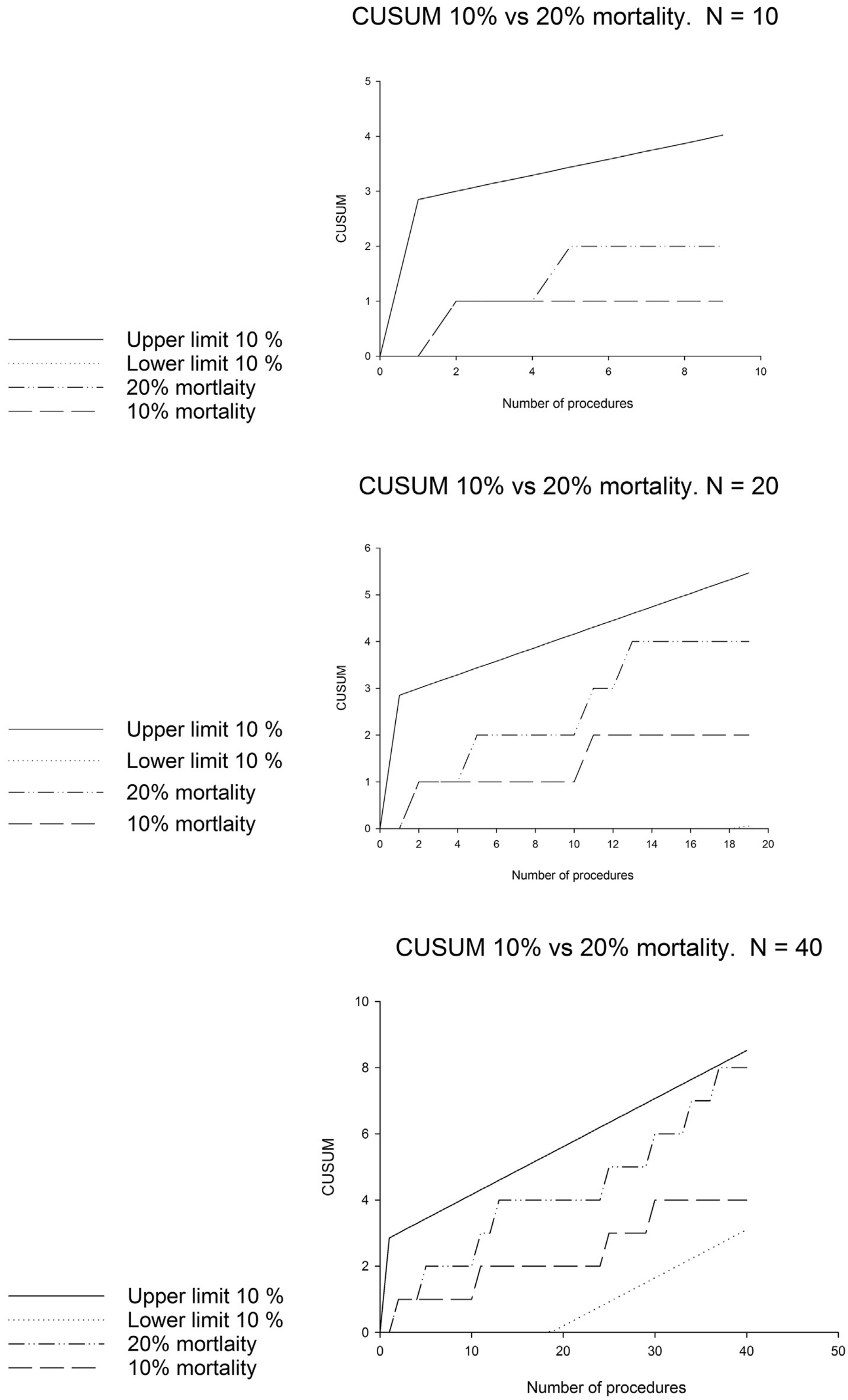

Fig. 7. The ability of CUSUM charts to detect a doubling of mortality rate within 40 patients.

The fallacy in assuming that variation in outcomes are invariably the result of the surgeon's performance is illustrated by the esophageal atresia mortality charts. The unadjusted charts suggest a process which is out of control. Adjusting for the effects of severe cardiac and renal anomalies suggests the reverse; the institutional performance is acceptable. We were fortunate in having robust data from our previous publication on esophageal atresia survival to permit the calculation of the risk coefficients for this condition [18]. For most surgeons, and most conditions a readily available model to produce the coefficients for survival probabilities will be lacking. This could be a practical task for national surgical associations to provide their members with the appropriate data for risk stratification, and to suggest the appropriate target and signal rate for individual conditions

In conclusion, there is a particular need for objective analysis of outcomes in a low volume specialty such as children's surgery. Statistical process control charts may allow surgeons to scrutinize their data with early detection of issues. The choice of an appropriate target rate however remains challenging.

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