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Monitoring excess unplanned return to theatre following colorectal cancer surgery

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Abstract

Objective

The objective of this study was to develop a risk-adjustment model for unplanned return to theatre (URTT) outcomes following colorectal surgeries in Australia and New Zealand hospitals and to apply the risk-adjustment to top-down and bottom-up statistical process control (SPC) methods for fair comparison of hospitals and surgeons' URTT rates.

Method

We analysed URTT outcomes from Australia and New Zealand hospitals who contributed data to the BCCA clinical registry between 2007 and 2016. Preoperative and intra-operative covariates were examined for risk adjustment of URTT. A risk-adjusted rate (RAR) funnel plot was prepared for between-hospital comparisons and identification of outlying hospitals with unusually high rates of URTT. Cumulative observed-minus-expected charts with CUSUM signals were then presented for surgeons within an outlying hospital.

Results

The study includes 15,134 patients who received colorectal surgery from 166 surgeons across 70 Australia and New Zealand hospitals. The weighted average URTT rate was 5.2%. The risk adjustment model identified 12 preoperative and intra-operative variables that significantly raise the risk of URTT: Male sex, ASA score, emergency admissions, conversion entry, left hemicolectomy, total colectomy, proctocolectomy, lower anterior resection, ultra-low anterior resection, APR, organ resection and excess lymph nodes harvested. Right hemicolectomy was the only procedure found to have a significantly reduced risk of URTT. URTT rates were not found to significantly vary across seniority of operator, however comparisons were confounded due to an imbalance in sample sizes. The funnel plot identified 5 hospitals as 'possible outliers' and hospital T was identified as a 'definite outlier'. The cumulative observed-minus-expected charts with CUSUM signals showed that within hospital T, 1 surgeon among 3 had a particularly bad run of URTTs.

Conclusion

Feedback from aggregated URTT outcomes using a RAR funnel plot is enhanced when follow-up examination of outlying hospitals is conducted with concurrent application of cumulative observed-minus-expected charts with CUSUM signals.

Key words:

Colorectal cancer surgery, unplanned return to theatre, funnel plots, CUSUM charts

Introduction

Unplanned return to theatre (URTT) within 30 days of colorectal surgery is often due to surgical complications, increases the risk of mortality and places a substantial burden on hospital resources [1–4]. As a surrogate quality indicator of surgical performance, URTT occurs relatively frequently and can generate enough cases for meaningful performance reviews of smaller volume hospitals [4].

Each year the Bi-National Colorectal Cancer Audit (BCCA) compares 30-day URTT rates for participating Australia and New Zealand hospitals [5]. Fair comparisons are made by taking into account variations in the risk profiles of hospitals using logistic regression. Hospitals' risk adjusted rates are then compared using risk-adjusted rate (RAR) funnel plots to identify hospitals that fall outside the 2 and 3 standard deviation control limits. While RAR funnel plots provide a suitable top-down approach for initial screening of outlying hospitals, they offer little in the way of knowing whether a bad run of excess URTT occurred during a specific period or if excess URTT can be attributed to a few surgeons or hospital-wide deficits in surgical care. To address this, Morton and colleagues recommend a bottom-up approach using statistical process control (SPC) methods [6]. Risk adjusted cumulative sum (CUSUM) charts represent a large variety of SPC methods that are increasingly used to monitor a range of surgical outcomes [7–9], including colorectal surgery [10,11]. Cumulative observed minus expected charts with CUSUM signals are used to monitor adverse outcomes and provide warning signals that allow for effective, well-timed interventions to improve patient safety [6]. This method may further enhance the auditing process of individual surgical performance within hospitals previously screened as outliers by a RAR funnel plot.

The primary aim of this study was to establish an effective predictive model of URTT for risk-adjustment. All available factors that define the casemix for the study population and the multilevel, patient-hospital hierarchy were considered. The secondary aim of this study was to explore the usefulness of a surveillance procedure that combined both top-down and bottom-up approaches to the statistical monitoring of excess URTTs.

Method

Ethics approval was obtained from the Royal Australasian College of Surgeons Human Research Committee.

Data source and patient selection

Data was sourced from the BCCA database containing a clinical registry of adult patients with colorectal cancer in Australian and New Zealand hospitals between 9 January 2007 and 27 May 2016. The dataset was structured in panel-data form, with 16,470 individual patient entries clustered across 180 consultant surgeons nested within 92 hospitals. Patient entries with missing URTT outcome, gender information or did not receive an operation (e.g., referred for palliative care) were excluded. Patients who did not return to theatre but died within 30 days of the operation were also excluded. Additionally, hospitals with less than 10 patient records were excluded given the potential for excessive shrinkage of URTT rates. Under these criteria, we identified 15,134 individual patients across 166 consultant surgeons from 70 hospitals for selection.

Pre- and intra-operative variables

The full set of pre- and intra-operative variables considered for risk-adjustment is located within the BCCA clinical registry (https://bcca.registry.org.au/). Patient characteristics included gender and age. Preoperative factors included service type (public vs private), American Society of Anesthesiologists (ASA) score and operative urgency (emergency or urgent and elective). Intra-operative factors included seniority of the lead operator, entry methods, procedure types, number of lymph nodes harvested and whether or not organs were resected or if a stoma was formed during surgery.

Outcome variable

The primary outcome of interest was unplanned return to theatre (URTT) within 30 days during the same admission as defined by clinical indicator 2.1 by the Australian Council on Healthcare Standards [12].

Statistical analysis

All statistical analyses were conducted using STATA version 14 [13] and R version 3.4.1 [14]. Descriptive statistics (means, standard deviations and percentages of URTT rates) were calculated for pre- and intra-operative variables. Hosmer and Lemeshow's (2000) variable selection method was carried out and variables found to be associated with URTT at a *p* value of less than 0.1 were considered for risk-adjustment [15]. Missing values were handled using the Multiple Imputation by Chained Equations (MICE) module in STATA with 10 imputations to ensure sufficient coverage of missing data [16]. Multivariate logistic regression was then used to build a risk-adjustment model of URTT until the most parsimonious and accurate model was determined using pseudo R^2 , Hosmer-Lemeshow goodness-of-fit and area under curve ROC statistics.

Generalised estimating equation (GEE) logistic regression was then used to fit the final risk-adjustment model to the dataset to estimate the expected URTT rate for each patient. Between-hospital comparisons were carried out using indirect standardisation of observed to expected rate ratios [17]. A RAR funnel plot of indirect standardised (percentage) rates for each hospital was then constructed with 95 and 99.8% control limits using the method described by Morton and colleagues (2013). Additional risk-adjusted cumulative observed minus expected (O-E) charts with CUSUM signals with a threshold h = 2.5 (150% increase control limit) were then constructed for consultant surgeons' excess URTTs from an outlying hospital. Further details of the statistical techniques and handling of missing data are provided in the online supporting information.

Results

Descriptive and univariate analyses

Of the 15134 patients who underwent colorectal surgery between 2007 and 2016, 785 (5.2%) patients required URTT. The mean age was 69.1 years (SD = 12.9 years; range: 19 – 102) and 8262 (54.6%) patients were male (Table 1).

There was no significant difference in the average age of patients who had URTT and those who did not. Patients who required URTT had a significantly higher average ASA score than those who did not (2.43 vs 2.23). The incidence of URTT was significantly higher for men (6%) than women (4.2%) and there was a significantly higher rate of URTT in public (5.8%) than private hospitals (4.7%). Emergency or urgent operations also had a significantly higher rate of URTT (6.5%) than elective patients (5%).

Seniority of the lead surgeon was not found to be significantly associated with URTT. A number of significant bivariate relationships existed between entry methods and procedure types. Both open (5.6%) and conversion (8.3%) entry methods yielded significantly higher rates of URTT, whereas laparoscopy resulted in a significantly reduced incidence of URTT (4.3%). Among the procedure types, right hemicolectomy was associated with a significantly lower incidence of URTT (3.3%), whereas a left hemicolectomy had a significantly higher incidence of URTT (7.9%). Total colectomy (9.6%), subtotal colectomy (9.6%) and proctocolectomy (10%) were found to be strongly associated with a higher incidence of URTT. A high anterior resection was strongly associated with a reduced incidence of URTT (4.1%), whereas low (6.3%) and ultra-low anterior resection (6%) were moderately associated with an increased incidence of URTT. Abdominoperineal resection (APR, 7.8%) and Hartmanns (8.2%) procedures were moderately associated with higher rates of URTT. We also found that the incidence of URTT increased when organs were resected (8.1%), or

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when a stoma was formed (7%) and, to a lesser extent, when more than 21 lymph nodes were harvested (6%).

<Table 1 here>

Risk-adjustment model of URTT outcomes

A total of 20 pre- and intra-operative variables were selected for inclusion in the initial risk-adjustment model: ASA score, gender, service type, urgency, open, laparoscopic and conversion entry methods, right and left hemicolectomy, total, subtotal and proctocolectomy, high, low and ultra-low anterior resection, APR and Hartmanns procedure types, whether or not organs were resected, a stoma was formed or lymph nodes harvested exceeded 21. Using the purposeful selection method of removing non-significant covariates a reduced model with logistic regression odds ratio estimates are presented in Table 2. The refined model did not present with collinearity issues and no higher order interactions were found. The pseudo R^2 statistic was small, with just 3% of the data explained by the risk-adjustment model. The model only achieved modest discrimination as measured by the area under the ROC curve (0.64, 95% CI: 0.62 – 0.66). However, the Hosmer-Lemeshow goodness of fit test indicated a good fit of the model to the data.

<Table 2 here>

Statistical process control charts

Figure 1 shows a RAR funnel plot of the risk-adjusted rates for each of the 70 hospitals, with outlying hospitals labelled according to their individual BCCA registry codes. Results show that 64 hospitals (91%) demonstrated only chance variation around the weighted average risk adjusted URTT rate (5.2%) and are classified as ‘in control’. Of the ‘in control’ sample, six hospitals of small patient volumes (median = 27 patients) did not report URTT events for the duration of the monitoring period and therefore had zero rate estimates each. Five hospitals (AU, AE, BX, BV and AM) were identified as ‘possible outliers’, had risk-adjusted rate estimates that lie outside the 95% control limits but within the 99.8% control limits. One hospital (T) was identified as a ‘definite outlier’, with a risk adjusted rate above the 99.8% control limits.

[Figure 1 goes here]

Figure 2 presents the cumulative observed-minus-expected charts with CUSUM signals for consultants 151, 210 & 228 in outlying hospital T. Upon examination of each chart it appears that the URTT rates for each consultant were variable over the course of the monitoring period. Consultant 151 is ‘in control’ and maintained a lower than expected URTT rate for the full duration of the monitoring period. While consultant 228 is also ‘in control’ it did appear that towards the end of the monitoring period there was a steady increase in URTT outcomes, but would not be enough to warrant concern. By contrast, consultant 210’s observed-minus-expected URTT goes ‘out-of-control’ by 10th September 2012, and continues to remain ‘out of control’ for the majority of the monitoring period. A CUSUM signal appears on the 17th July 2014 indicating that the odds of URTT was 2.5 times that of the risk-adjusted rate for the same length of time. Investigation of consultant 210’s excess URTT outcomes prior to the signal show that given the consultant’s case mix, the risk-adjusted rate was expected to be 6.9%, and therefore operations were relatively difficult given that the BCCA average for URTT is 5.2%. However, by 17th July 2014 consultant 210’s individual observed rate was 20.8%, more than 2.5 times that of the risk-adjusted rate, resulting in the CUSUM signal.

[Figure 2 goes here]

Discussion

In this study, we demonstrated the development of a risk-adjustment model that was applied to both top-down and bottom-up approaches to the statistical monitoring of URTT following colorectal surgery in Australia and New Zealand hospitals. The combined approach is likely to improve the efficiency of monitoring as it allows auditing bodies to focus on outlying hospitals, rather than an arbitrary review of surgeons’ performance which may leave them open to accusations of bias. This also reduces the multiplicity of statistical testing that would otherwise increase the likelihood of false-positive warnings of excess URTT. Methods that reduce the rate of false-positive alerts may improve trust among surgeons and willingness to contribute their performance data to the monitoring process and therefore improve the reliability of the surgical outcomes data overall [6].

We found that the weighted average 30-day URTT rate of 5.2% is lower than other population-based rate estimates of 5.7 to 6.5% [2–4]. However, we did not include readmission outcomes as over half were missing and did not include date or clinical details regarding readmission. In an institutional review of surgical outcomes, Lin and colleagues (2017) found that up to 35.3% of reoperation outcomes were recorded incorrectly and that 60% of false unplanned reoperations was due to a lack of adequate documentation [18]. We hope that by focusing only on the initial admission we minimised the potential for including URTTs that were not related to the index operation. We also acknowledge that while we took every opportunity to reduce false URTTs, the true rate of URTT may be higher due to under-reporting.

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There was substantial variation in URTT rates across patient characteristics and operative variables. Surprisingly, univariate analysis showed that seniority of the lead surgeon was not associated with the likelihood of URTT. This could be in part due to a counterbalance in case complexity and the level of experience of the lead operator, whereby senior consultants are called upon to operate on riskier cases. However, with more than 80% of cases operated on by consultant surgeons, adequate comparisons of URTT rates across levels of seniority is confounded by unequal sample sizes. The online supporting information shows further commentary on factors associated with an increased or reduced risk of URTT.

We demonstrate the benefits of pairing a top-down approach with a bottom-up approach to identify surgeons within outlying hospitals that have an especially poor run of URTT. Results from the RAR funnel plot would recommend an investigation into the reasons for the unusually high rate of URTT in hospital T. The observed-minus-expected cumulative sum chart with CUSUM signals found substantial variation in URTT rates across the three surgeons with hospital T. Two surgeons (210 and 228) demonstrated progressively higher rates of URTT over time, whereas one (151) remained below the expected average throughout the monitoring period. Surgeon 210 had a considerable bad run of excess URTTs, when the CUSUM signal occurred surgeon 210 had over 4 excess URTTs above average.

We acknowledge a number of limitations to this study. The analysis of URTT outcomes was carried out retrospectively, whereas in a prospective scenario a CUSUM signal would normally trigger an investigation before reseting the process for another phase of monitoring. The application of the CUSUM in this study is to demonstrate how the information gathering process used by auditing bodies could be enhanced once outlier hospitals are identified. However, in this context its effectiveness as a mechanism to warn of poor surgical performance for immediate intervention is severly limited. We also cannot assure that the hospitals we identified as outliers would remain as outliers if there were no data quality issues to contend with (e.g., missing values). However, it is noteworthy that even with an alternative risk-adjustment model for URTT outcomes the BCCA identified the same hospitals, along with several others, as having outlying URTT rates [5]. Data completeness, accuracy and timeliness will continue to challenge the BCCA surgical auditing system, even with the application of these new methods to their annual reporting of surgical performance.

It is important to note there is currently no standardised set of surgical outcomes measures in use to assess surgical centres and specific surgeons carrying out colorectal operations. McNair and colleagues (2016) looked at a wide range of outcomes for colorectal surgery and by using a combination of Delphi methods and consensus meetings, involving surgeons, nurse specialists and patients they generated a 12 domain “core outcome set” [20]. Within this they have identified anastomotic leak, perioperative survival, surgical site infection, stoma rates and complications, and conversion to open operation (where appropriate) as the most important operative outcomes. They did not list URTT rates among their “core outcome set”. Nonetheless, we feel URTT rates are a useful surgical outcome measure as they provide an objective end-point that is easily defined and therefore easily auditable and are usually indicative of surgical performance. Our results have shown significant variation in URTT rates between hospitals and surgeons, even when adjusted for complexity indicating that some hospitals and surgeons are performing clearly better than others. We feel that it is important to ascertain why this is, in an attempt to improve results nationwide.

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“List of Supporting Information”

Supporting Information

Table 1. Pre- and intra-operative univariate associations with unplanned return to theatre (URTT) for 15134 patients in the BCCA dataset, 2007 – 2016.

Variable	No URTT n = 14349 (94.8%)	URTT n = 785 (5.2%)	p value*
Age, mean (sd) years	69.1 (12.9)	69.4 (13.2)	0.49
ASA, mean (sd) score	2.23 (0.8)	2.43 (0.8)	< 0.001
Gender, n (%)			
Male	7765 (94%)	497 (6%)	
Female	6584 (95.8%)	288 (4.2%)	< 0.001
Service, n (%)			
Public	6523 (94.2%)	401 (5.8%)	
Private	7826 (95.3%)	384 (4.7%)	0.002
Urgency, n (%)			
Elective	12470 (95%)	659 (5%)	
Emergency/Urgent	1683 (93.5%)	117 (6.5%)	0.008
Most senior operator, n (%)			
Consultant	11332 (94.7%)	640 (5.4%)	
Supervised fellow	1684 (95.5%)	80 (4.5%)	
Unsupervised fellow	378 (95.5%)	18 (4.6%)	
Supervised registrar	740 (95.5%)	35 (4.5%)	
Unsupervised registrar	38 (92.7%)	3 (7.3%)	0.47
Entry method, n (%)			
Open	7191 (94.8%)	430 (5.6%)	< 0.001
Laparoscopic	5522 (95.7%)	247 (4.3%)	< 0.001
Hybrid	413 (95.4%)	20 (4.6%)	0.60
Conversion	616 (91.7%)	56 (8.3%)	< 0.001
Robotic	79 (96.3%)	3 (3.7%)	0.54
Transanal	173 (96.7%)	6 (3.4%)	0.27
taTME	12 (85.7%)	2 (14.3%)	0.12
Procedure type, n (%)			
Right hemicolectomy	4265 (96.6%)	152 (3.4%)	< 0.001
Extended right hemicolectomy	702 (94.2%)	43 (5.8%)	0.45
Left hemicolectomy	496 (92.4%)	41 (7.6%)	0.009
Sigmoid colectomy	104 (94.6%)	6 (5.2%)	0.9
Total colectomy	609 (90.4%)	65 (9.6%)	< 0.001
Subtotal colectomy	424 (90.4%)	45 (9.6%)	< 0.001
Proctocolectomy	126 (90%)	14 (10%)	0.01
High Anterior Resection	2645 (95.9%)	112 (4.1%)	0.003
Low Anterior Resection	1258 (93.7%)	85 (6.3%)	0.05
Ultra-low Anterior Resection	2010 (94%)	129 (6%)	0.05
APR	849 (92.2%)	72 (7.8%)	< 0.001
Hartmanns	492 (91.8%)	44 (8.2%)	0.001
Colo-anal anastomosis	42 (95.5%)	2 (4.5%)	0.85

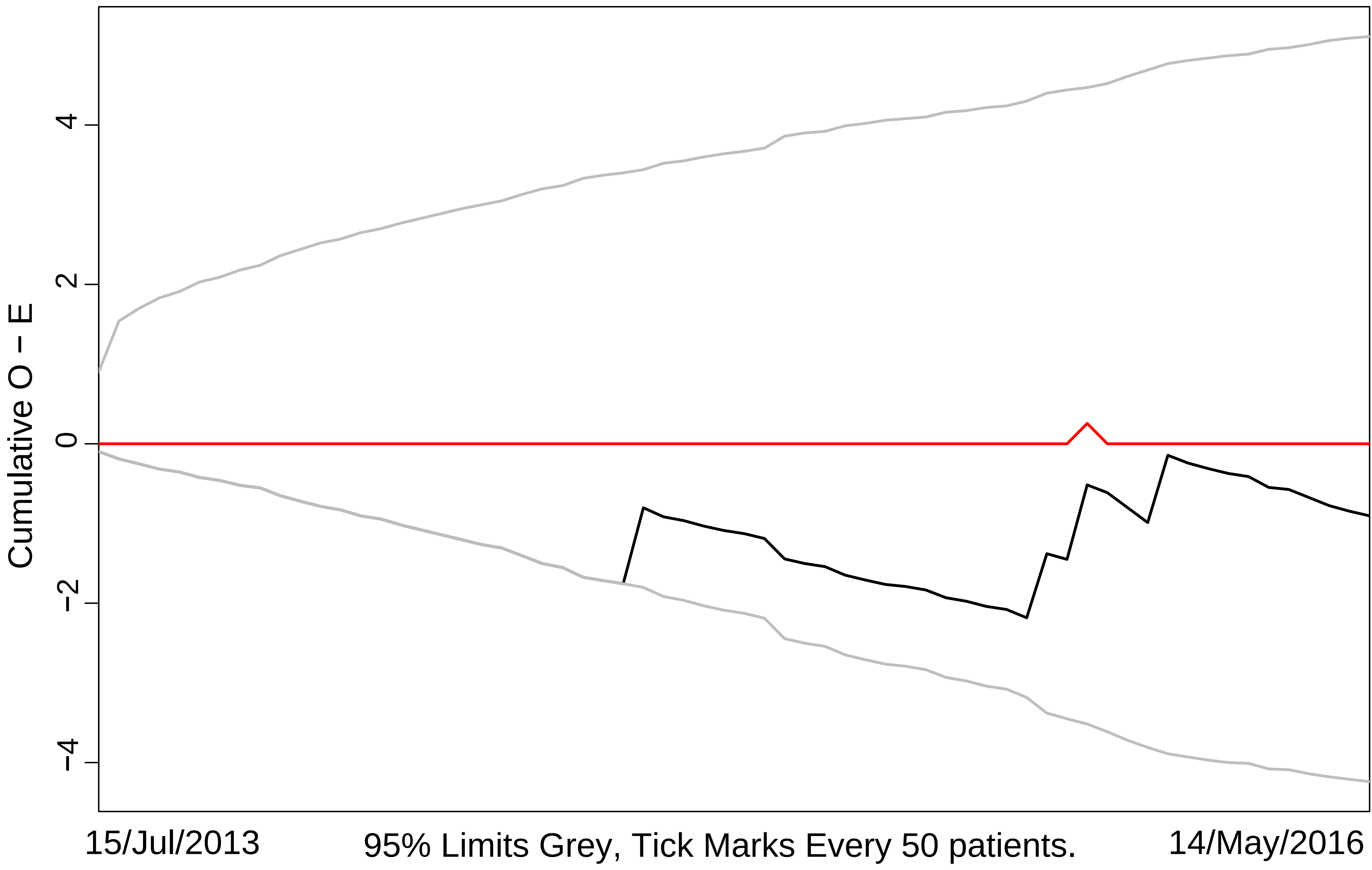
Transverse Colectomy	143 (96%)	6 (4%)	0.53
Local excision	133 (94.3%)	8 (5.7%)	0.79
TEMS or TAMIS	140 (96.6%)	5 (3.4%)	0.35
Organs were resected, n (%)	697 (92.9%)	61 (8.1%)	0.001
Stoma was formed, n (%)	3864 (93%)	291 (7%)	< 0.001
Lymph nodes harvested > 21, n (%)	3128 (94%)	199 (6%)	0.02

* Student's t-test or X^2 test

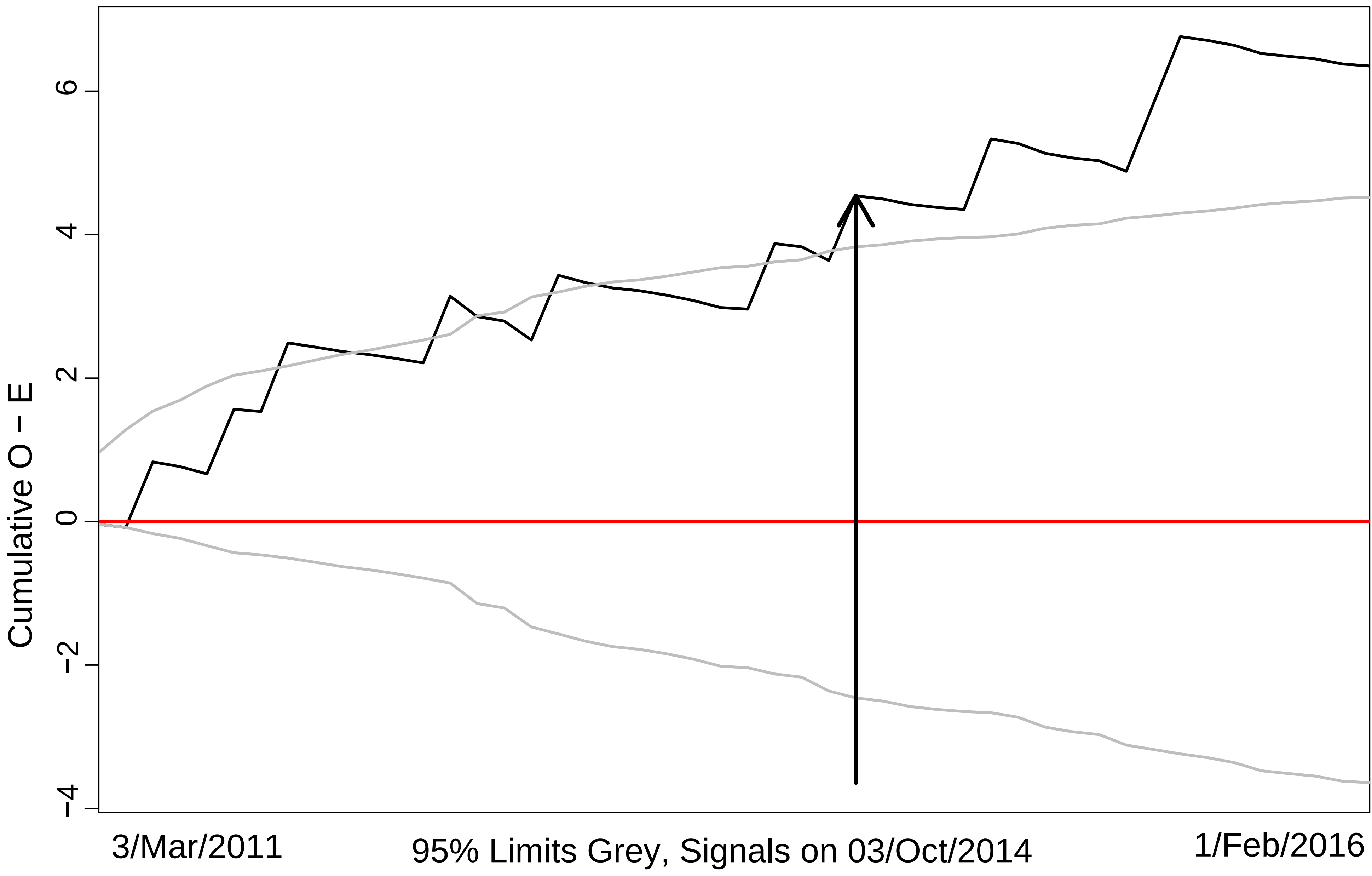
Table 2. Multivariate logistic regression analysis of pre- and intra-operative patient data (N = 15134) for URTT

Factor	Adjusted OR (95% CI)	Wald test of difference	
		t-test	P value
Male vs female	1.38 (1.20 - 1.57)	4.63	< 0.001
ASA score	1.31 (1.23 - 1.40)	8.54	< 0.001
Urgent/emergency vs elective	1.28 (1.06 - 1.54)	2.60	0.009
Conversion entry	1.62 (1.20 – 2.19)	3.11	0.002
Right hemicolectomy	0.77 (0.66 – 0.89)	-3.42	0.001
Left hemicolectomy	1.75 (1.20 – 2.55)	2.92	0.004
Total colectomy	2.07 (1.56 – 2.75)	5.05	< 0.001
Proctocolectomy	2.30 (1.35 – 3.90)	3.08	0.002
Lower anterior resection	1.54 (1.23 – 1.90)	3.78	< 0.001
Ultra-low anterior resection	1.54 (1.22 – 1.94)	3.64	< 0.001
APR	1.86 (1.26 – 2.74)	3.13	0.002
Organs were resected	1.44 (1.12 – 1.85)	2.87	0.004
Lymph nodes harvested > 21	1.23 (1.02 – 1.48)	2.19	0.029

Consultant: 151 Cumulative O − E chart



Consultant: 210 Cumulative O − E chart



Consultant: 228 Cumulative O − E chart