Assessing the surgical outcomes of Minimally Invasive Total Mesorectal excision in the long term– Going beyond the initial learning curve

Vivek Sukumar[1], Sanket Bankar[1], Praveen Kammar[2], Swapnil Patel[1], Mufaddal Kazi[1], Jitender Rohila3, Ashwin Desouza[1] and Avanish Saklani[1]

[1]Department of Surgical Oncology, Tata Memorial Hospital, Mumbai, India, [2]Saifee Hospital, Mumbai India [3]Department of Surgical Oncology, HBCH, Sangrur, Punjab, India

Introduction:

Laparoscopic colorectal surgery requires a certain degree of understanding of surgical anatomy, dexterity, and technical skills. An initial training period is usually required for the majority of surgeons to become proficient in these complex procedures by continuous repetition of these tasks. Consequently, there has been much debate as to how much experience should be considered adequate to overcome the associated learning curve and perform laparoscopic rectal surgery safely.

In this study we aimed to. :

- **To assess the learning curve in minimally invasive total mesorectal excision.**
- **To review the long term outcomes of minimally invasive using risk adjusted CUSUM once the surgical team has crossed the initial learning curve**

Materials and methods:

A retrospective analysis of prospectively collected data of TME performed by laparoscopy or robotic surgery over ten years from 2010 to 2020

All patient who have undergone minimally invasive total mesorectal excision – laparoscopic and robotic were included. We excluded patients who had undergone Extended and Beyond TME, cases where complete TME was not performed and cases where records were incomplete..

The demographic and various risk factors (variables) associated with laparoscopic and robotic surgery were analyzed. The factors were summarized according to scale of measurement. The four outcomes evaluated were **hospital stay, blood loss, high grade complication and leak**.

All the outcomes were categorized for ease of analysis. The relevance of risk factors with each of these outcomes was established by incorporating the correlation structure between risk factors and each outcome. The variable importance was scaled between 0-100 and only those variables (factors) with importance value more than 50, for a particular outcome, were considered for adjusted analysis.

Multiple regression analysis was performed to derive probability score for each patient for a specific outcome. The score indicates the likelihood of outcome for an individual patient based on his/her levels of risk factors.

To determine the learning curve for any new or ongoing surgical activities, cumulative sum (CUSUM) charts were used. CUSUM is a statistical tool that graphically represents the sequential monitoring of cumulative performance of any dichotomized or continuous variable under assessment.

It emphasizes failures penalizing them against the correct performance when individual risk is adjusted - sensitive to negative changes. The primary control input when constructing a CUSUM chart is the control limit. The control limit signals performance deterioration once crossed by the CUSUM.

In our study, the control limits for risk adjusted and non-risk adjusted CUSUM charts were constructed by considering desired target odds multiplier as 2, and the estimated accepted failure probability based on Phase I (2010 - 2016) data. The control limits for each surgical outcome was obtained by simulating a false signal probability (0.05) depending on the sample size and above accepted failure probability.

For risk adjusted CUSUM charts, individual probability score was used as accepted failure probability for each patient. All statistical analyses were carried out using *caret* and *cusum* library from R-software (ver 3.3.3).
The statistical significant was evaluated at 5% level.

The analyses were performed independently for laparoscopic and robotic surgeries.

Two distinct time periods were identified :

2010 – 2016 (Phase I) – Case 0 to 335
2016 – 2020 (Phase II) – Case 335 to 726

Result :

In laparoscopic surgery, a post-operative hospital stay of more than 8.9 days, blood loss of > 162.5ml, post operative complications with Clavien Dindo grade > 3 and leaks was regarded as outcome event. For blood loss, the key risk factors were type of surgery, location, nodal output and ASA status.

The adjusted odds of hospital stay > 8.9 days in ULAR and ISR surgeries were 3.618 [95% C.I: 1.101 - 11.883; p=0.0341] and 1.685 [95% CI: 1.017 - 2.794; p=0.043] times higher as compared to reference APR surgery.

For the outcome pot operative complications, AR and ISR showed significantly increased odds of towards outcome with adjusted OR 2.886 [95% CI: 1.192 – 6.988; p=0.0188] and adjusted 4.588 [95% CI: 1.929 – 10.91; p=0.0006] respectively.

For blood loss > 162.5 ml as outcome event, the risk associated with pre-operative radio therapy was 7.694 [95% CI: 3.775 – 15.681; p < 0.0001] times higher than those without therapy.

For leak as outcome, all sphincter preserving surgery types showed statistically significant effect on the outcome as compared to sphincter sacrificing type.

In robotic surgery, the pre-operative radio therapy had 3.132 [95% CI: 1.098 – 8.928; p=0.0327] times higher adjusted odds towards increased hospital stay, while signet had significantly reduced odds of the outcome with adjusted OR of 0.268 [95% CI: 0.086 – 0.833; p=0.0229].

Further, LAR surgery type had significant impact on high grade with OR of adjusted 19.25 [95% CI: 1.347 – 275.2; p=0.0293] as compared to APR type. The other preserving surgeries also had high influence on the outcome, but statistically insignificant. Pre-preserving radio therapy had a significant effect on blood loss as indicated by adjusted OR of 19.08 [95% CI: 2.494 – 146.02; p=0.0045].

Hospital Stay :

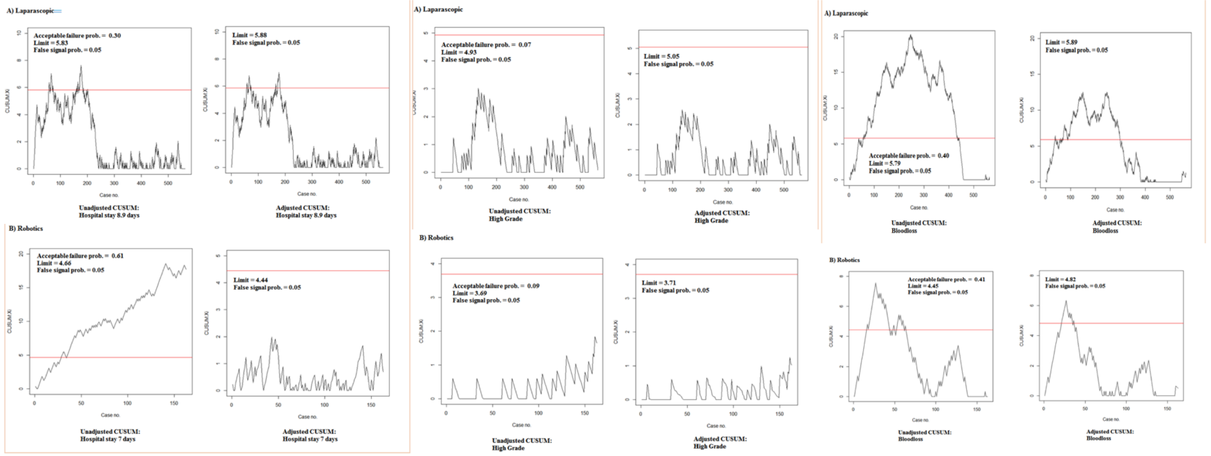
The CUSUM limits obtained for both unadjusted and risk adjusted graphs were 5.83 and 5.88 respectively. The risk adjusted CUSUM revealed increase in the curve at early stages till patient 67 (2010-2013). A smooth curve fit indicated a small plateau around 100th patient.

In robotics, the process was well within the upper CUSUM limit (4.44) throughout suggesting good control on the outcome.

Post operative Complications :

In laparoscopic category, there was increase in the curve from 100th patient and reached a peak by 124th patient. Throughout the observation window, the CUSUM was well within under the upper limit (5.05).

In the robotics type, there was no such plateau observed during the period 2014-2019 .



Blood loss :

In laparoscopy, After 300th patient, the outcome was within limits and under control till the end of observation window (2017-2019).

In Robotics, In robotic surgeries, the adjusted CUSUM curve revealed a small plateau between patients 25 to 50 (2015-2016), which showed a sharp decline subsequently and was within the upper CUSUM limit (4.82).

Leaks :

In laparoscopy, a first plateau attained between 120th to 220th patients (2015-2016). And a second plateau was a second plateau seen between 375th to 460th patients (2018).

There were no leaks in the robotic group.

Long term outcomes :

The four long term outcomes were studies for long term once the surgical team had crossed the initial learning curve. There were multiple points of plateau but none of which crossed the reference CUSUM limit.

Conclusion :

The initial plateau of learning curve in TME appears to be around 60 to 100 patients but there are intermittent peaks reflecting a need to constantly monitor the surgical quality well beyond the initial learning curve.