

Original Research Article

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'Taking a calculated risk'- Is American College of Surgeon's National Surgical Quality Improvement Program universal risk calculator a valuable tool to improve quality of surgical services in Indian surgical scenario?

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ABSTRACT

Background: American College of Surgeon's National Surgical Quality Improvement Program (ACS NSQIP) risk calculator is a valuable tool exercised in the hospitals across the USA for predicting risk rates for 8 post-operative complications till the 30th post-operative day, taking into account 21 risk factors. Its applicability in the surgical practice in India has not been popular. This study explores, if this model is accurate in predicting risk of post-operative complications in surgical patients in India.

Methods: Retrospective study done on 368 patients who underwent elective and emergency surgical procedures in a medical college hospital. Demographic data, contemplated surgery, co-morbid factors entered into the risk calculator and predicted personal risk calculated and compared to average risk. Post-operative progress reports retrieved. Complications till 30th post op day compared with the predicted risk estimates. Brier score, sensitivity and specificity, PPV/NPV, z and p values calculated for the probabilistic, predictive values of the model for validation.

Results: Emergency procedures done in 143 and elective in 225. 67 developed major, 35 minor, 11 fatal complications. The average Brier score was 0.00324. Mean sensitivity was 96.08 %, specificity 98.94%. Mean PPV 82.6%, NPV 99.6%. The predictions were inaccurate for serious, "any" complications, discharge to nursing and rehabilitative facility, the colectomy ileus and length of stay. The percentage of error ranged from 2.22 to 25.

Conclusions: Overall, the ACS NSQIP surgical risk calculator very fairly predicted the complications till the 30th post-operative day which naturally matched with actual complications that were seen.

Keywords: American college of surgeon's national surgical quality improvement program, Surgical risk calculator, Universal risk calculator

INTRODUCTION

American College of Surgeon's National Surgical Quality Improvement Program (ACS NSQIP) has been evolved as an empiric need driven, open access, objective, procedure specific and general risk factor driven risk calculator which is a software-based calculator utilized for predicting risk of post-operative complications.¹ It is a valuable tool exercised in the NSQIP hospitals across the

USA to predict the post-operative adverse events and complications during the post-operative period. This takes into account 21 risk factors variables and displays the risk rate for that patient regarding 8 post-operative complications.² This was first implemented in 2013 and have shown to be widely favored, where the prediction of the risk of patient developing the complications till the 30th post-operative day is done and has found favours as the predicted percentage of all risks individually

correlates well with the actual complications that occurred. This ultimately helps in improving the overall quality of surgical care. The program began with 4 hospitals across USA and then spread across some 700 hospitals in over 10 countries and this number is steadily growing. This tool is a guide to the surgeon in arriving at decision which is an inescapable component of the counselling and informed consent.^{1,2,3} Several workers have published studies validating its use for a range of procedures.⁴ This may be an important tool for surgical education in addition to "quality improvement" in surgical practice. This is yet to be discovered.⁵

A study found that many of the hospitals have no robust data regarding the surgical complications and therefore they cannot analyse and take corrective measures. If the reliable data are not forthcoming, the quality cannot be improved. These hospitals realized this fact only when they joined the ACS -NSQIP program. The ACS NSQIP has been developed by the surgeons who well appreciated the surgeons' difficulties and can gauge the quality levels and improve upon them. The ACS NSQIP program is different from other quality improvement programs as it collects data from patient's charts and has identified more complications, it has an inbuilt system to adjust risks as per the patient profile and risk stratification, it also takes into account the complexity of surgery (case mixed adjustments) and takes into account the adverse outcomes till the 30th post-operative day.⁶ The ACS NSQIP surgical risk calculator estimates the chances of a patient who may develop adverse outcome or complication till the 30th post-operative day, unfavorable outcome (such as a complication, death) or prolonged hospital stay after surgery.² This takes into account, the age, sex, significant previous personal history, like smoking, height, body weight (BMI), diabetes, hypertension, renal failure, sepsis preceding the surgery, whether the patient would require ventilatory support etc.

The nature of the surgery (emergency or elective) is also taken into consideration. This also provides opportunity for adding the specific geriatric risk factors for patients above 65 yrs. There is also a provision for the surgeon to adjust the risk quantum, if he/she considers, in case the risk has been underestimated or overestimated. The basis of this calculator is the data on the outcome of a large number of patients who have undergone similar surgery in similar conditions.⁵ There have been reports from various workers concluding various levels of accuracy and validity of its ability to predict the complications. NSQIP is an open access calculator. Therefore, it has been employed for calculation of the risk assessment in hospitals across other countries besides the USA. The peer-reviewed studies showed that ACS NSQIP has been instrumental in improving the surgical care quality, reducing incidence of complications and costs.⁴

The ACS NSQIP empowers both the surgeon and the patients to make the decisions regarding the post-operative adverse outcomes in each of the situations

based on the risk calculator which is specific to each patient.⁷ The adoption of the ACS NSQIP risk calculator has helped in averting hundreds of complications, thereby preventing mortalities, morbidities and thereby bringing down the cost of medical care by millions of dollars.⁸ Its usefulness in risk assessment among the patients in Indian hospitals have not been fully studied. This study has been done with the sole aim, if this model is accurate in predicting surgical risks in surgical patients in India.

Objectives of the study were to calculate the predicted risks till the 30th post-operative day for complications on the patients who underwent surgical procedures along with the average risk percentage, To study the adverse events actually occurred till the 30th post-operative days and to calculate the sensitivity, specificity and validity of the risk predictions and its accuracy.

METHODS

Approval from the institutional ethics committee obtained. A retrospective study done on 368 patients who underwent elective and emergency surgical procedures during the period from January 2017 through December 2019 in a tertiary care medical college hospital in a rural location. Inclusion criteria were the male and female patients who presented with the conditions for the first time, underwent elective or emergency procedures. Exclusion criteria were, where the complete 30-day post-operative follow up records were not available, or those who were lost to follow up, or those who were transferred elsewhere.

Data collected for demographic status, risk variables, nature of contemplated surgery, emergency/elective, co-morbid factors entered into the online American College of Surgeons NSQIP risk calculator and predicted personal risk calculated. It was compared with the average risk mentioned in the risk calculator result. The surgeon specific risk adjustment done wherever required. Operative notes and post-operative progress reports retrieved.

The patients followed up till 30th post op day and incidences of post-operative complications (major complications, any complications, cardiac, renal failure, pulmonary, venous thromboembolism, surgical site infections, urinary tract infection, return to OR, discharge to nursing/rehabilitative service, colostomy ileus and anastomotic leak- as applicable, death and length of stay) recorded and compared with the predicted risk estimates. Brier score, sensitivity and specificity, positive and negative predictive values and p and z values calculated to measure the discrimination and calibration of the predictive model and the probabilities, for validation.

The research is being reported in line with the relevant SQUIRE (standards for quality improvement reporting excellence) guidelines.

RESULTS

Of the total 368 patients, 143 (38.85%) underwent emergency (Table 1) and 225 (61.14%) underwent elective surgical procedures (Table 2).

Table 1: List of emergency procedures performed.

S. no.	Name of the procedures	No
1	Perforated peptic ulcers (Exploratory laparotomy, peritoneal toilet, closure of perforation and drainage)	34
2	Acute intestinal obstruction – adhesiolysis	16
3	Above knee amputation (diabetic foot)	11
4	Below knee amputation (diabetic foot)	15
5	Splenectomy total (traumatic rupture)	9
6	Appendectomy (with ruptured appendicitis)	20
7	Meckel's diverticulectomy	3
8	Exploratory laparotomy for ruptured amebic liver abscess	2
9	Exploratory laparotomy, resection and anastomosis of small gut	11
10	Strangulated inguinal hernia, exploration, resection anastomosis small gut and herniorrhaphy	7
11	Excision of Fournier's gangrene	8
12	Sigmoidoscopy for sigmoid volvulus and end to end colo-colic anastomosis	2
13	Ileoileal intussusception, resection anastomosis (ileal)	1
14	Obstructed/ strangulated umbilical hernia, exploration, reduction/resection and repair	4
Total		143

Males numbered 54.62% (n=201) and females 45.38% (n=167). Age ranged 02 yrs through 72 yrs (mean 46 yrs). Weight ranged from 10 kgs through 76 kgs (mean 52 kg). 5.70% (n=21) patients had partial dependent status. Mean height 162 cms. 7.88% (n=29) patients had the ASA Score of IV. 2.44% (n=9) patients showed SIRS. 24.45% (n=90) patients were smokers. 16.30% (n=60) patients were diabetics (on insulin 7 and on OHA 53). 19.29% (n=71) were hypertensives. Severe chronic obstructive pulmonary disease was present in 1.35% (n=5). Sepsis over previous 48 hrs was evident in 4% (n=15). Dyspnoea on moderate exertion was present in 1% (n=4). 1 patient (0.27%) had congestive cardiac failure, acute renal failure in 1 patient (0.27%). None had required dialysis. None had disseminated cancer or

previous major cardiac event. (Table 3) shows the demographic and pre morbid data of patients.

Serious complications were seen in 11.96% (n=44), any complications in 13.86% (n=51), pneumonia in 2.72% (n=10), cardiac complications in 1.91% (n=7), surgical site Infection in 4.62% (n=17), urinary tract Infection in 1.36% (n=5), venous thromboembolism in 1.09% (n=4), renal failure 0.82% (n=3), readmission 6.26% (n=23), return to OR 3.81% (n=14), death in 4.35% (n=16), discharge to nursing or rehab Facility in 12.78% (n=47), sepsis in 1.91% (n=7), colectomy ileus in 13.59% (n=50), anastomotic leak seen in 3.31% (n=12). Figure 1 shows the graphical comparison between predicted no. and actual no. of patients with post-operative complications.

Table 2: List of elective procedure performed.

S. no.	Name of the procedures	No.
1	Superficial Parotidectomy	6
2	Total Thyroidectomy	17
3	Open drainage of pseudocyst pancreas	3
4	Repair of Para umbilical hernia	11
5	Varicose veins, Saphenofemoral flush ligation, stripping of GSV, hook phlebectomies	20
6	Laparoscopic cholecystectomy	52
7	Laparoscopic cholecystectomy with cirrhosis liver	1
8	Hydatid cyst liver multiple, PAIR and pericystectomy	3
9	Modified radical mastectomy	21
10	Right hemicolectomy with ileotransverse anastomosis	12
11	Mesh repair of incisional ventral hernia	23
12	Partial distal gastrectomy with Polya Roux en Y anastomosis	5
13	Anterior resection for carcinoma rectum	3
14	Abdominoperineal resection with end colostomy	8
15	Laparoscopic inguinal hernia repair (TAPP)	5
16	Lichtenstein Inguinal hernia mesh repair-- open	23
17	Inguinal exploration for incompletely descended testis and orchiopepsy	3
18	Trans abdominal proctoectomy-open	1
19	Left hemicolectomy with colocolic anastomosis	8
Total		225

Table 3: Demographic and pre morbid data of patients.

Patient parameters and morbid status	Range
Total number of patients	368
Age (years)	02 Years-72 Years (mean 46 years)
Male/female	Male- 201 (54.62%), Females-167 (45.38%)
Height (m) range	1.50 - 1.74 meters in adults (162cms)
Weight (kg)range	10 kg - 76 kgs (mean 52 kg)
Independent functional status	Partially dependent status –21 (5.70%)
ASA score/SIRS	ASA IV in 29 (7.88%); SIRS-9 (2.44%)
Hypertension requiring medication	71 (19.29%)
Smoker within 1 year	90 (24.45%)
Diabetes	60 (16.30%), on OHA-53 (14.40%); on Insulin 7 (1.90%)
Previous cardiac event	Nil
Severe chronic obstructive pulmonary disease	5 (1.35%)
Congestive cardiac failure in previous 30 days	1 (0.27%)
Dialysis required	Nil
Disseminated cancer	Nil
Ventilator dependent	4 (1.086%)
Acute renal failure	3 (0.81%)
Ascites within previous 30 days	1 (0.27%)
Sepsis within previous 48 h	15 (4.076%)
Dyspnea on moderate exertion	4 (1.086%)
Emergency procedures	143 (38.86%)
Elective procedures	225 (61.14%)

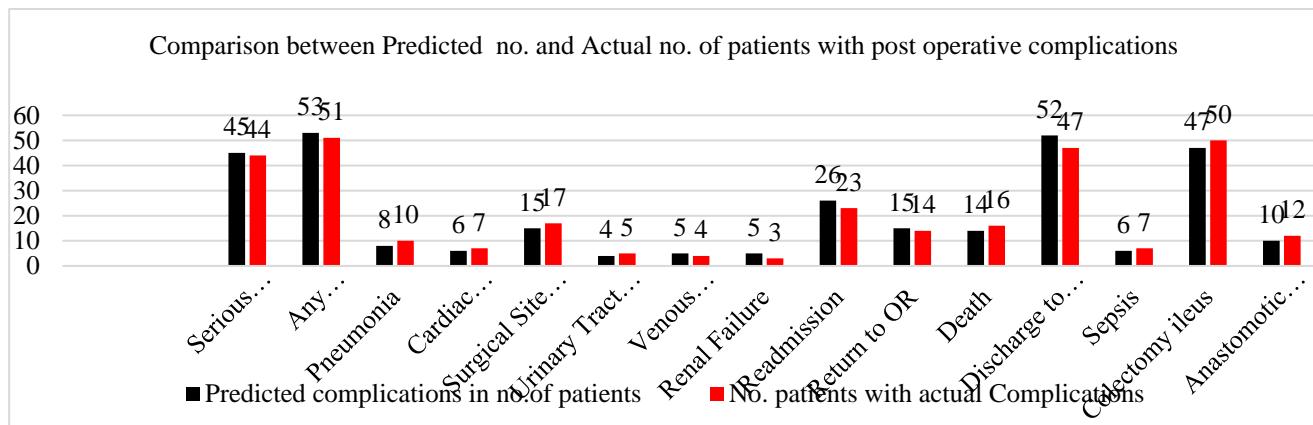
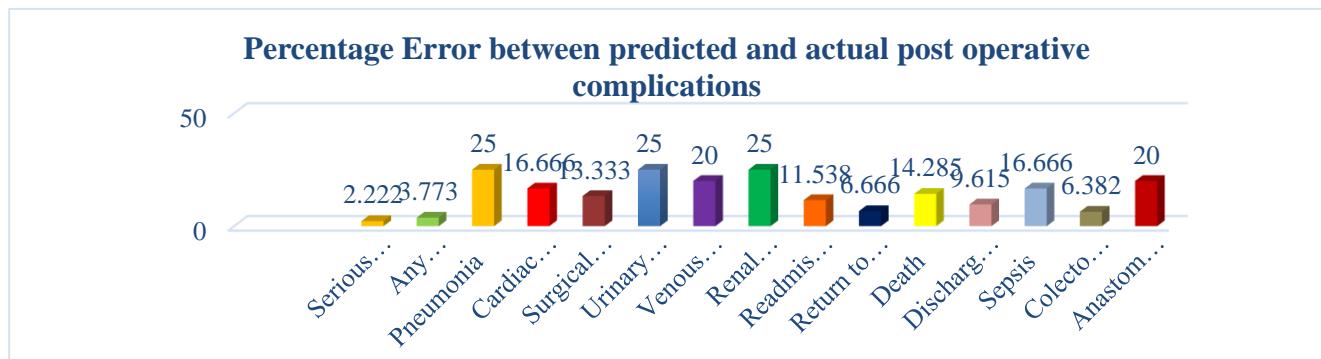
**Figure 1: Comparison between predicted no. and actual no. of patients with post-operative complications.****Figure 2: Percentage error between predicted and actual post-operative complications**

Table 4: Actual and predicted rates of various post-operative complications in percentage and numbers, percentage error, sensitivity, specificity, positive and negative predictive value (PPV/NPV), p and z values with significance.

Nature of Post-operative complications	Actual Complications rate (%) and no	Predicted Complications rate (%) and no	Percent age error	Sensitivity	Specificity	PPV	NPV	Z-Value	P-Value	Significance
Serious Complications	11.96 (n=44)	12.08 (n=45)	2.222	86.36	96.60	77.55	98.42	0.0542	0.96012	NSS
Any Complications	13.86 (n=51)	14.54 (n=53)	3.77	82.35	93.69	67.74	97.05	0.264	0.7948	NSS
Pneumonia	2.72 (n=10)	2.18 (n=08)	25	70	99.44	77.77	99.16	0.0186	0.9840	NSS
Cardiac Complication	1.91 (n=07)	1.60 (n=06)	16.66	85.71	99.16	66.66	99.72	0.2996	0.7642	NSS
Surgical Site Infection	4.62 (n=17)	3.93 (n=15)	13.33	76.47	99.14	81.25	98.86	0.4627	0.6455	NSS
Urinary Tract Infection	1.36 (n=05)	0.91 (n=04)	25	80	99.17	57.14	99.72	0.5762	0.5619	NSS
Venous thromboembolism	1.09 (n=04)	1.27 (n=05)	20	75	99.72	75	99.72	0.2434	0.8103	NSS
Renal Failure	0.82 (n=03)	1.26 (n=05)	25	66.66	99.72	66.66	99.72	0.6017	0.5485	NSS
Readmission	6.26 (n=23)	7.04 (n=26)	11.53	91.30	97.68	72.41	99.41	0.4302	0.6672	NSS
Return to OR	3.81 (n=14)	3.96 (n=15)	6.66	85.71	98.30	66.66	99.42	0.1095	0.9124	NSS
Death	4.35 (n=16)	3.84 (n=14)	14.28	93.75	98.86	78.94	99.71	0.3422	0.7278	NSS
Discharge to Nursing or Rehab Facility	12.78 (n=47)	14.03 (n=52)	9.615	91.48	94.39	70.49	98.69	0.507	0.6171	NSS
Sepsis	1.91 (n=07)	1.73 (n=06)	16.66	71.42	98.06	41.66	99.43	0.1695	0.8650	NSS
Colectomy ileus	13.59 (n=50)	12.72 (n=47)	6.38	82	96.85	80.39	97.1	0.3451	0.7263	NSS
Anastomotic leak	3.31(n=12)	2.46 (n=10)	20	75	98.87	69.23	99.15	0.6466	0.5157	NSS

For major complications these were serious complications (sensitivity 86.36, specificity 96.60, PPV 77.55%, NPV 98.42%, $p=0.9012$), Any Complications (sensitivity 82.35%, specificity 93.69%, PPV 67.74%, NPV 97.05%, $p=0.7948$), pneumonia (sensitivity 70%, specificity 99.44%, PPV 77.77%, NPV 99.16%, $p=0.9840$), cardiac (sensitivity 85.71%, specificity 99.16%, PPV 66.66%, NPV 99.72%, $p=0.7642$), SSI (sensitivity 76.47%, specificity 99.14%, PPV 81.25%, NPV 98.86%, $p=0.6455$), urinary tract infection (sensitivity 80%, specificity 99.17%, PPV 57.14%, NPV 99.72%, $p=0.56192$), venous thromboembolism (sensitivity 75%, specificity 99.72%, PPV 75%, NPV 99.72%, $p=0.8103$), renal (sensitivity 66.66%, specificity 99.72%, PPV 66.66%, NPV 99.72%, $p=0.5485$), readmission (sensitivity 91.30%, specificity 97.68%, PPV 72.41%, NPV 99.41%, $p=0.6672$), return to OR (sensitivity 85.71%, specificity 98.30%, PPV 66.66%, NPV 99.42%, $p=0.09124$), death (sensitivity 93.75%, specificity 98.86%, PPV 78.94%, NPV 99.71%, $p=0.7278$), discharge to nursing or rehabilitation (sensitivity 91.48%, specificity 94.39%, PPV 70.49%, NPV 98.69%, $p=0.6171$), sepsis (sensitivity 71.42%, specificity 98.06%, PPV 41.66%, NPV 99.43%, $p=0.8650$), colectomy ileus (sensitivity 82%, specificity 96.85%, PPV 80.39%, NPV 97.16%, $p=0.72634$), anastomotic leak (sensitivity 75%, specificity 98.87%, PPV 69.23%, NPV 99.15%, $p=0.5157$). Figure 2 shows graphically the percentage error between predicted and actual post-operative complications. Figure 3 shows predicted and actual mean of (LOS) length of hospital stay (in days).

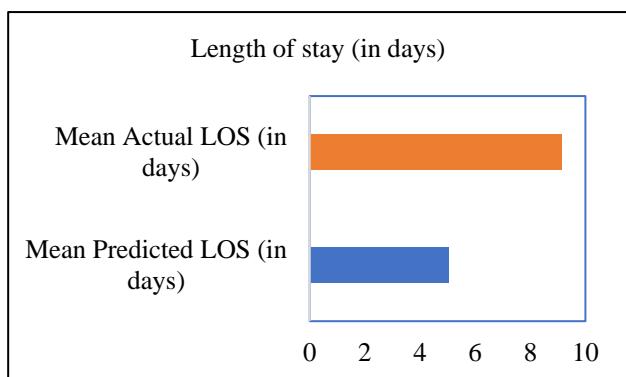


Figure 3: Predicted and actual mean of (LOS) length of hospital stay (in days).

DISCUSSION

The ACS NSQIP calculator has shown fairly accurate results as is evident from the results predicted by the calculator and the actual occurrence of the complications. The calculator showed good correlation between the pre morbid states, the contemplated procedures, whether it is an emergency or elective procedure and the predicted and actual no. of patients who suffered complications.

Serious complications, cardiac, renal complications, surgical site infections, urinary tract infections, venous thromboembolism, readmissions, return to OR, discharge to nursing/rehabilitation facility, colectomy ileus, anastomotic leaks were slightly overestimated. Whereas "any" complications, pneumonia, deaths, sepsis were slightly underestimated. Some discordance between the predicted and actual occurrence was found in "any" complications (14.54 vs 13.86%), cardiac complications (1.6075 vs 1.91%), discharge to nursing and rehabilitation facility (14.0325 vs 12.78%) ,in the sense, that these were slightly overestimated (predicted to be very high) and so were the return to OR (3.96 vs 3.81%). Similarly, length of stay was also grossly underestimated. Pneumonia (2.1897 vs 2.72%), Urinary tract infection (0.9125 vs 1.36%), renal failure (1.265 vs 0.82%), venous thromboembolism (1.2775 vs 1.09%) showed higher percentage of error.

Overall, the NSQIP risk calculator had shown high specificity, comparatively lower sensitivity. Brier score proved the calculator to be of good probabilistic value. The predicted incidence and the actual incidence of 30-day post-operative complications showed comparable results. The p and the z values were not significant as far as the predicted versus actual number of patients with complications are considered. Giovanni et al in a study in Italy observed that in emergency setting the ACS NSQIP risk predictor was accurate in predicting adverse post-operative outcomes.² El-Ghobashy et al in a retrospective study compared the surgical outcomes using SORT (Surgical Outcome Risk Tool) and ACS -NSQIP scoring system in a retrospective comparative study in 84 patients who underwent gynaecologic oncological procedures. The SORT and ACS-NSQIP scores calculated before the procedures were done. The time taken for the procedures, blood loss, hospitalization period and complications were recorded. They observed that accuracy of prediction using the ACS NSQIP was better than the SORT scoring.⁹

A study for testing the usefulness of the ACS NSQIP in predicting the post-operative complications by Prasad et al in head and neck cancer, found that the calculator was inaccurate in predicting the individual risk and the overall incidence of complications. Velanovich et al in a study had identified that ACS NSQIP risk assessment scoring system does not take into account "how difficult the surgery was?" or "how excellently was it done?", "the post-operative course", "nursing management", "post-discharge follow up management", and "rehabilitative aspects". Ultimate outcome following surgical procedure is the result of interplay of so many factors which do not influence the risk calculator.^{1,3,4} In the current procedural terminology (CPT) coding system which is a key input variable for the surgical procedure, it was experienced that multiple surgical procedures if contemplated in the same patient cannot be populated in the NSQIP software.³

Subramaniam et al in their study involving the use of ACS NSQIP calculator in head and neck oncologic conditions have eminently observed that prior radiotherapy to the area to be operated, microvascular anastomosis or chemo radiotherapy did influence the wound outcome which may cause flap necrosis, wound breakdown or wound infection altering the need of reoperation etc.³

It was noteworthy that the average length of stay was not accurately predicted by the calculator. The actual observed average LOS was 9.1 days whereas the prediction was for 5.02 days. This gross discordance could be because of more patients are dealt as “day care surgery” and then referred for discharge to nursing care or rehabilitation centre in the United States, which is not the practice in India, where home care is not easily accessible to most. The length of stay predicted for cases where the patients who underwent distal gastrectomy was only 4 days, whereas the actual LOS was 8 days. For total thyroidectomy the prediction was for 1 day, but the actual stay was for 6 days. Even where a colonic anastomosis was performed, the actual stay was 10 days, but the prediction was for 5 days.

The ACS NSQIP calculator showed good prediction for 30-day post-operative adverse events in our study but certain shortcomings were observed too. Certain dreaded complications like anastomotic breakdown following the small bowel anastomosis were not even listed among the complications. The CPT code does not allow us to enter multiple procedures contemplated on same patient, thereby it undercalculates the risk of these complications. It has no adjustments for the surgeon's competence related factors like a junior specialist performing or an experienced surgeon doing the same, thereby influencing the complications rate. When the co morbid factors are considered, the calculator does not take into account for example, in case of diabetic subjects, whether the diabetic status is under control or not. In certain elective procedures, pre-operative chest physiotherapy would also minimize the post-operative pulmonary complications, this factor has not been accounted for in this calculator. The calculator has no consideration for certain factors like, the duration of the surgical procedure, any blood transfusion etc. which can influence the incidence of complications.

CONCLUSION

The ACS NSQIP has been designed to equip the practicing surgeons with a software based easy tool to predict the post-operative adverse reactions while contemplating a surgical procedure on a patient. This takes into considerations, various pre morbid conditions, nature of the procedures, and some 21 parameters, before it predicts some 8 post-operative complications. It arms the patient on making informed decisions, educating the surgery consultants and residents in counselling the

patients regarding the outcome of the procedures so that all out efforts are made beforehand to minimize the effects of them. This ultimately is aimed at improving the overall quality of care of the surgical patients. Our study done in an Indian teaching hospital demonstrates that the ACS NSQIP surgical risk calculator very fairly predicted the post-operative complications till the 30th post-operative day which naturally matched with actual complications that were seen.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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