2017

www.jmscr.igmpublication.org Impact Factor 5.84 Index Copernicus Value: 83.27 ISSN (e)-2347-176x ISSN (p) 2455-0450 crossref DOI: \_https://dx.doi.org/10.18535/jmscr/v5i8.16

J IGM Publication

Journal Of Medical Science And Clinical Research An Official Publication Of IGM Publication

### A Study of the Correlation between Pre-Operative Risk Factors and Various Complications Occurring during and after Laparoscopic Procedures

Authors

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#### Abstract

**Background:** Laparoscopic surgeries have experienced a boom since the 1990's. The benefits of laparoscopic approach were so readily apparent that laparoscopic procedures soon became the standard of care without any randomized controlled trials comparing it to the previous gold standard procedures (e.g. Cholecystectomy). Laparoscopy by definition is minimally invasive surgical approach which is being used in many minor and major surgeries. The significant advantages seen in laparoscopic surgeries are minimal blood loss, reduced hospital stay, less post-operative pain, disability and quicker recovery as compared to open surgeries. As more and more surgeries are being done laparoscopically the incidence and magnitude of complications is also expected to increase. It is of crucial importance that the complications associated with laparoscopic surgeries be identified in time to prevent serious patient sequelae and morbidity. A complication is defined as a new problem or illness that makes the treatment of a previous or pre-existing condition more difficult. Complications of laparoscopic procedures can be broadly divided as general complications of laparoscopy and complications specific to the procedure itself. With this background knowledge from the literature we conducted this study to evaluate various complications and pre-existing risk factors.

Aims and Objectives: (1) To study, the correlation between pre-operative risk factors and various complications occurring during and after laparoscopic procedures. (2) To study the incidence and enumerate various complications occurring during intra-operative and post-operative period in laparoscopic procedures (3) To classify various complications occurring based on the different steps and different procedures. (4) To study the correlation between various pre-operative risk factors and the different complications occurring in laparoscopic procedures.

**Materials and Methods:** This study was conducted after getting approval from institutional ethical committee. This was a prospective cohort study comprising of 600 patients undergoing laparoscopic procedures at a tertiary care centre over a period of 2 years. The patients undergoing basic laparoscopic procedures as well as advanced laparoscopic techniques were included in this study depending upon defined inclusion and exclusion criteria. We focused on the type of complications in relation to the

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procedure and the time of occurrence. The inpatient and outpatient visits of every patient were followed up, to assess intra-operative and post- operative complications. Procedures were classified as basic laparoscopic procedures (cholecystectomy, appendectomy, diagnostic laparoscopy, IPOM, and hernia surgeries) and advanced laparoscopic procedures (abdomino-perineal resection, gastrectomy, anterior resection, nephrectomy, splenectomy, esophagectomy, metabolic surgery, CBD explorations and pyelolithotomy).complications were evaluated and listed according to specific procedures and grouped with respect to the surgical step during laparoscopy to distinguish access trauma (trocar related injuries), dissection trauma (injury during dissection) associated trauma (hypercarbia, hypotension, pulmonary embolism) and wound related complications.

**Results:** Out of 600 studied cases 310 (51.67%) were males and 290 (48.33%) were females with a m:f ratio of 1:0.93. Most common age group of the patients was between 41-50 (23%) years followed by 31-40 (19.17%) years and 21-30 (18.83%) years. Complications were seen in 41 (6.83%) patients. Analysis of preoperative risk factors revealed that anemia was present in 184 (30.7%) patients while hypoprotinemia was present in 101 (16.8%) patients. Diabetes was found to be present in 16 (2.7%) patients. The cases were divided into ASA scores. 567 (94.5%) patients belonged to ASA I while 27 (4.5%) and 6 (1%) patients belonged to ASA II and III respectively. The duration of surgery was found to be less than 2 hours in 201 (33.5%) patients while the duration was 2-6 hours and more than 6 hours in 384 (64%) and 15 (2.5%) patients respectively. The complications found in basic laparoscopic procedures were most common in diagnostic laparoscopies (8.69%) followed by hernia repair (8.51%) and laparoscopic cholecystectomy (5.52%). The overall complication rate seen in basic laparoscopic procedures was found to be 5.59%. In advanced laparoscopic procedures the highest complication rate was seen with miscellaneous procedures (23.5%) followed by laparoscopic combined procedures (20%) and colorectal surgeries (9.52%). The most common complications seen were wound infections/healing (2.16%) followed by visceral injuries (1.66%) and miscellaneous complications (1.66%) less common complications included vascular and access related injuries (0.33% each). Most complications (4.5%) occurred during early post-operative period (up to 6 weeks) followed by during late post operative period (1.33%) and intra-operative period (1%). Mortality was low (0.33%) that too was seen in patients suffering from malignant diseases.

**Conclusion:** Laparoscopic surgeries have a definite advantage over conventional surgeries. The main advantages include low rate of post-operative infections, less blood loss, short hospital stay and reduced morbidity. Our study concludes that most of the benign and malignant intra-abdominal pathologies can be safely dealt by laparoscopy with acceptable complication rates. Rational selection of patients, experienced surgeons, proper pre-operative work up and a low threshold for conversion will further reduce the incidence of complications.

Keyword: laparoscopic surgeries, complications, pre-operative risk factors, outcome.

#### Introduction

Though reports of laparoscopic procedures date back to the beginning of the 20<sup>th</sup> century, laparoscopic surgery has experienced a boom since the 1990's. The benefits of laparoscopic readily apparent approach were so that laparoscopic procedures soon became the standard of care without any randomized controlled trial comparing it to the previous gold standard procedures (e.g. Cholecystectomy). Basic and advanced laparoscopic surgeries are safe but not risk free<sup>[1]</sup>. The enthusiasm of laparoscopic procedures has been tempered somewhat with the reports of unique complications associated with this approach<sup>[2]</sup>. Various complications seen during laparoscopic surgeries include general complication like complications of anesthesia, patient positioning, complications of access, complications of pneumoperitoneum and trocar site injuries. The complications specific to the procedure are unique to the individual procedure and may differ from procedure to procedure <sup>[3]</sup>. Only few papers have dealt with the aspects of

Only few papers have dealt with the aspects of risk factors for intra and post-operative complications of laparoscopic surgeries<sup>[4]</sup>. Moreover correlation between pre-operative risk factors and the various complications occurring during and after laparoscopic procedures has not

been studied by many investigators. Lack of consensus about defining and grading postoperative complications have made the task difficult for many investigators. It is imperative for operating surgeons to anticipate the complications in patient undergoing laparoscopic surgeries. The importance of knowing beforehand association of certain risk factors with the complications in laparoscopic surgeries can never be overemphasized <sup>[5]</sup>.

With this background knowledge we conducted a study evaluating the various complications which occur during and after laparoscopic procedures and to find a correlation between pre-existing risk factors.

#### **Materials and Methods**

This study was conducted at a tertiary care hospital in an urban area. Study was approved by institutional ethical committee. A total of 600 laparoscopic procedures were studied and followed up over a period of 2 years. These included basic laparoscopic procedures as well as advanced laparoscopic techniques. We focused on the type of complication in relation to the procedure and the time of occurrence. The inpatient and outpatient visits of every patient were followed up, to assess intra-operative and post- operative complications.

Procedures were classified as basic laparoscopic procedures (cholecystectomy, appendectomy, diagnostic laparoscopy, IPOM, hernia surgeries) advanced procedures and laparoscopic (abdomino-perineal resection, gastrectomy, anterior resection, nephrectomy, splenectomy esophagectomy, metabolic surgery, CBD explorations and pyelolithotomy). Complications were evaluated and listed according to specific procedures and grouped with respect to the surgical step during laparoscopy to distinguish access trauma (trocar related injuries), dissection trauma (injury during dissection) associated trauma (hypercarbia, hypotension, pulmonary embolism) and wound related complications.

### **Inclusion criteria**

All patients who were pre-operatively planned for routine laparoscopic procedure.

### **Exclusion criteria**

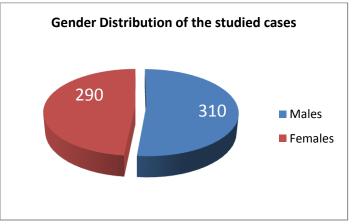
- 1. Patients who were excluded from laparoscopic procedures during preanesthetic check up.
- 2. All patients who were converted to open surgery due to inability to complete laparoscopic dissection.
- 3. Patients not giving consent for the study.
- 4. Emergency procedures.

The data was collected in a proforma and analyzed using sophisticated software and results were graphically represented whenever required.

#### Results

This study was carried out at a tertiary care centre over a period of 2 years. A total of 600 patients who underwent laparoscopic procedures were studied. The patients who were converted to open surgery due to inability to complete the procedure laparoscopically were excluded from the study. Procedures converted to open for delivering the dissected specimen or extracorporeal anastomoses were included in the study.

Out of total 600 patients 310 (51.67%) were males and 290 (48.33%) were females with a M: F ratio being 1:0.93.



**Figure 1** Gender Distribution of the studied cases. The age distribution of the studied cases showed that in males the most common age group was 41-50 (68/310) years followed by 21-30 (61/310) years and 31-40 years (58/310). In females the most common age group undergoing laparoscopic

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surgeries was found to be 41-50 years (74/290) followed by 31-40 years (57/290) and 21-30 years (52/290).

Age (in years)	Male	Female	Total
1-10	7	2	9
11-20	16	30	46
21-30	61	52	113
31-40	58	57	115
41-50	64	74	138
51-60	56	43	99
61-70	38	29	67
71-80	9	3	12
81-90	1	0	1
Total	310	290	600

Table 1: Age groups of the studied cases

Study of preoperative risk factors revealed that most common factors affecting rate of complications were anemia, hypoprotinemia, diabetes, ASA score, duration of surgery and experience of the operating surgeons.

Anemia was defined as having a preoperative hemoglobin level below 10gm% in female patients and below 11gm% in male patients. Also any patient requiring pre-operative blood transfusion was also considered as having anemia. The incidence of anemia in our study group was 30%. Anemia was present in 184 patients (30.7%).

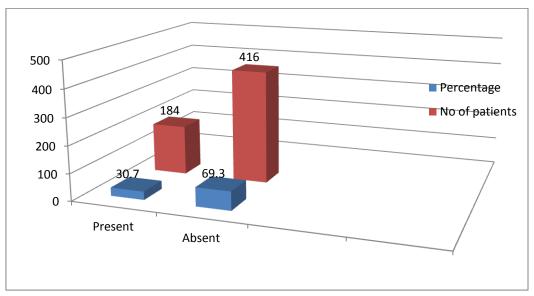
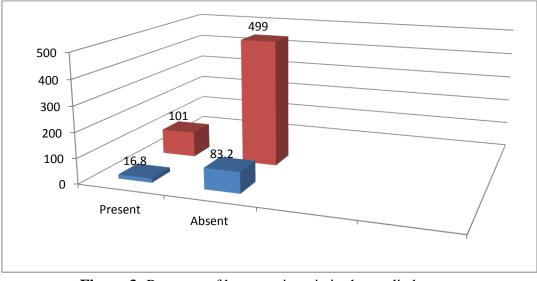
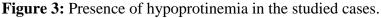


Figure 2 : Presence of anemia in the studied cases.

Hypoprotinemia was considered to be present in any patient who had a total protein level less than 6 gm%. (For both male and female population).





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Any patient who was a known diabetic on oral hypoglycemic medication or insulin; or any patient who had a deranged blood sugar level diagnosed for the first time during pre-anesthetic evaluation was considered to have a positive risk factor of diabetes. In our study diabetes was found to be present in 16 patients (2.7%).

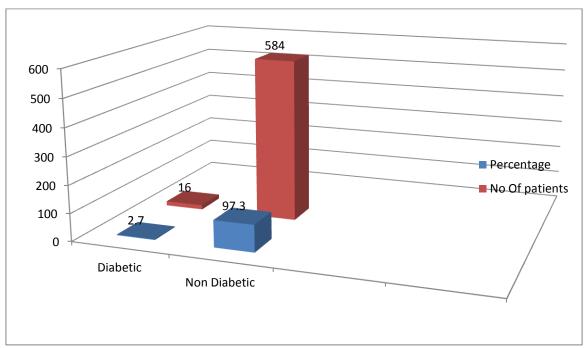


Figure 4 : Presence of diabetes in the studied cases.

ASA score is based on the pre-operative status of the patient as given by the American society of anesthesiologist. As one can see 94.5% of the patients are belonging to class i. This is because the patient profile caters to elective surgery in fit patients. Only ASA class I, II and III were included. The other patients were unfit for either general anesthesia; or considered high risk for laparoscopic surgery and hence were excluded from the study.

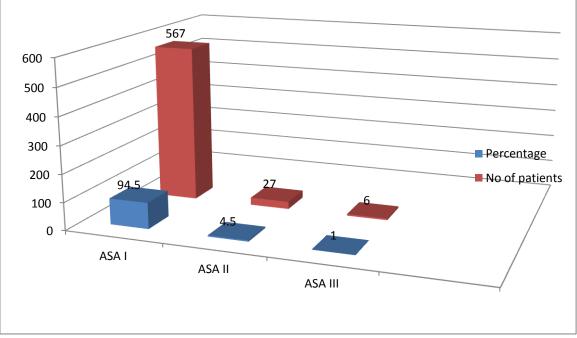
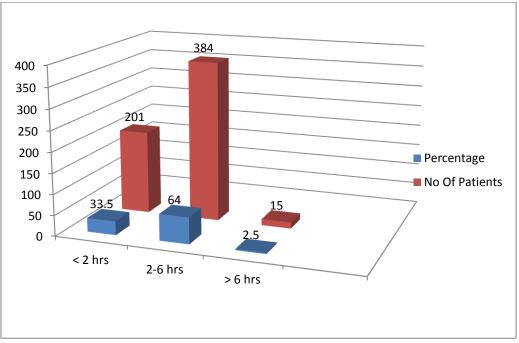
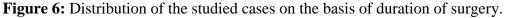


Figure 5: Distribution of the cases on the basis of ASA score.

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Many studies have shown that prolonged duration of surgery was a risk factor for certain postoperative complications like surgical site infection, deep vein thrombosis, and anesthetic complications. Laparoscopic surgeries are considered to be prolonged compared to their open counterparts. In our study majority of the surgery fell in the 2-6 hours category (64%). There were 33.5% which were completed within 2 hours, while only 2.5% were prolonged surgeries which lasted over 6 hours (Most of these being metabolic surgery).





Experience of the surgeon is considered an important factor for complications occurring. In our study all the surgeons performing laparoscopic procedures were experienced in this art. Each surgeon having an experience of at least 10 years and capable of teaching their skills to their students. Hence the factor of learning curve could not be assessed.

The most frequent procedures performed were laparoscopic cholecystectomy, laparoscopic appendectomy, totally extra-peritoneal hernia repair, trans-abdominal pre-peritoneal hernia repair and procedures over the gastrointestinal tract. Table 1 & 2 shows considerable differences related to the different degrees in technical difficulty. Easy procedures such as adhesiolysis and appendectomy have the lowest complication rate of 0% and 1.4% respectively. The complication rate varied between 3.8% to 5.5% for difficult procedures like laparoscopic IPOM, cholecystectomy, and hydatid cyst excision. As expected, the complication rates for very difficult procedures (gastrointestinal surgeries and surgeries on the renal system) were significantly higher.

Sr.no	Procedure	Total surgeries	Complication	Frequency
1.	Lap cholecystectomy	217	12	5.52%
2.	Lap appendectomy	69	1	1.44%
3.	Lap hernia repair	94	8	8.51%
4.	Diagnostic lap	23	2	8.69%
5.	Lap hydatid excision	26	1	3.84%
	Total	429	24	5.59%

**Table 2 :** Complications during basic laparoscopic procedures.

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Sr.no	Procedure	Total surgeries	Complication	Frequency
1.	Lap upper GI procedures	33	3	9.09%
2.	Lap small bowel and mesenteric surgeries	6	0	0
3.	Lap colorectal surgeries	42	4	9.52%
4.	Lap pancreatic and major hepato-biliary procedures	27	1	3.70%
5.	Lap metabolic surgeries	11	1	9.09%
6.	Lap urological procedures	25	2	8%
7.	Lap combined procedures	10	2	20%
8.	Miscellaneous	17	4	23.5%
	Total	171	17	9.94%

**Table 3 :** Complications during advanced laparoscopic procedures.

The overall complication rate was 7%. The complication rate for basic procedures was found to be 5.59% while that for advanced laparoscopic procedures was 9.94%

Various complications seen during laparoscopic procedures are presented in tabulated form (Table 3). Wound infection was found to be the most common complication associated with laparoscopic surgeries (12/42) followed by miscellaneous complications (11/42) and biliary lesions (5/42).

**Table 4:** Type of complications seen in thestudied cases.

COMPLICATION	TOTAL	PERCENTAGE
	NUMBER	
Vascular injuries	2	2 (0.33%)
Access injuries		2 (0.33%)
Accidental peritoneal tear	2	
Visceral injuries		10(1.66%)
Biliary lesions	5	
Upper GI lesions	2	
Lower GI lesions	3	
Urinary lesions	0	
Infection/Healing		13 (2.16%)
Wound infection	12	
Hernia related to trocar	1	
Associated trauma		4 (0.66%)
Hypotension	1	
Hypercarbia	1	
Pulmonary embolism	1	
Thrombosis	1	
Miscellaneous	11	11 (1.83%)
Total	42	42 (7%)

The complications were further categorized based upon the steps of surgery when they occurred and their period of presentation. Most of the complications manifested in the early postoperative period (up to 6 weeks), nearly 4.5%, late post operative complications came next(1.33%), while intra-operative complications were only 1%. The re-intervention rate was 2.33% while the major complication rate was 2.5%. This is comparable to most studies which gave the rates of major complications at 2%.

**Table 5:** Timing and type of complications in thestudied cases

PERIOD OF INTEREST	COMPLICATIONS	FREQUENCY
Intra-operative		6 (1.0%)
positional	1	
Surgical	4	
Anesthetic	1	
Early post-operative		27 (4.5%)
period (up to 6 weeks)		
Bleeding	2	
Pain	1	
thrombosis	2	
Biliary leak	5	
Anastomotic leak	5	
Post-op infection	12(2%)	
Late post-operative		8 (1.33%)
period (beyond 6 weeks)		
Chronic Pain	2	
Recurrence	4	
Port site hernia	1	
Others	1	
TOTAL	41	41 (6.83%)

#### Discussion

A total of 600 patients who underwent laparoscopic procedures were studied. Certain preoperative and intra-operative risk factors were analyzed. The study mainly consisted of studying complications involved in various laparoscopic surgeries. For this purpose Complications were broadly classified as general complications of laparoscopy, Complications specific to the

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procedure and complications of wound healing. The general complications of laparoscopy were further subdivided into anesthetic complications, complications related to Patient positioning, complications access, physiological of complication of pneumoperitoneum and trocar site injuries. In our study we found 1 anesthetic complication (0.16%) which is acceptable rate according to various authors <sup>[6]</sup>. In our study we found 1 patient who developed intra-operative hypotension in the reverse trendelenberg position. Head up position associated with trendelenberg position is associated with pooling of blood in the periphery leading to reduced venous return, cardiac output and BP, the severity of which depends upon the steepness of the tilt. These hemodynamic changes may cause hypotension<sup>[7]</sup>. disturbances hemodynamic can These be ameliorated by preloading the patient with isotonic fluid and achieving pneumoperitoneum in the supine position rather than in the reverse trendelenburg position. During our study no penetrating trocar injuries were reported. Two accidental peritoneal breaches were reported while creating extra-peritoneal space for surgery. These complications rates were within acceptable limits as reported by Jansen et al<sup>[8]</sup>. In our study we had 4 complications which could be attributed to pneumoperitoneum 1 case of hypercarbia was seen a prolonged surgery of MGB with IPOM, 2 cases of DVT were reported in our study and 1 case of laparoscopic appendectomy with postoperative shoulder pain These complication rates were comparable to the studies conducted by Patel et al <sup>[9]</sup>.

In our study we performed 217 laparoscopic cholecystectomies, with 12 patients reporting some sort of complications. That gave a procedure specific complication rate of 5.52%. Of these 6 were wound related complications while 1 patient developed DVT. Complications during dissection were 5 (2.3%). This is comparable to the studies conducted by Cuschieri et al <sup>[10]</sup>, Strasberg et al<sup>[11]</sup> who had complications rates of 4.5%. No complications were reported during dissection of

appendix laparoscopic ally. There was 1 complication in patients undergoing laparoscopic appendix, which was due to pneumoperitoneum. The results were comparable to study conducted by Gupta et al <sup>[12]</sup> who found complication rate during laparoscopic appendicectomy to be 1.71%. There were a total of 68 inguinal hernia repairs done laparoscopically. A total of 7 complications were reported. Of these 2 were accidental peritoneal breach during TEP, and have been described earlier. There were 2 patients with recurrence (2.9%) both after TEP. 2 patients with chronic pelvic pain and 1 port site infection. The results were comparable to studied done by Leibl et al <sup>[13]</sup> and McCormack et al <sup>[14]</sup>. We did 2 laparoscopic intraperitoneal only mesh surgeries. During these surgeries 1 complication was reported which was a port site infection which was managed with antibiotics and dressing. The infection rate was comparable to the study done by Roberts et al<sup>[15]</sup> though there was no statistical significance. There were 26 patients with hydatid who disease successfully underwent а laparoscopic procedure. Of the only 1 patient reported with a biliary leak, which was managed conservatively. This complication rate (3.85%) was far less than what was reported by Palanivelu et al<sup>[16]</sup> and Seven R et al<sup>[17]</sup>. Amongst the advanced laparoscopic procedures, there were a total of 42 patients who underwent laparoscopic colorectal procedures. No complications were seen in patients or APR, rectopexy and right hemicolectomy. 3 of the 10 patients who anterior resection underwent developed complications. Two had anastomotic leaks while a female patient developed rectovaginal fistula. Another patient who underwent left hemicolectomy developed recurrence. The overall complication rates during advanced laparoscopic procedure were comparable to Greenberg et al <sup>[18]</sup> and Tekkis et al <sup>[19]</sup>. There were a total of 33 upper GI procedures performed. Of which there were 3 complications reported which were comparable to similar studies done by Legget et al <sup>[20]</sup> and peters et al <sup>[21]</sup>. Pancreatic and major

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hepato-biliary procedures are not routinely done via laparoscopy and there are few studies regarding these procedures. In total we had 27 procedures in this group. Majority of these procedures was for benign pathologies and only 1 patient got complicated bringing the complication rate to % which is far less than those reported by Viljakka M et al<sup>[22]</sup> and Lacy A M<sup>[23]</sup>. There were 25 urological procedures performed of which 2(8%) complications were reported. 1 of which involved a migrated DJ stent and the other was a surgical site infection. At our institution there were 11 metabolic surgeries performed, which included 10 mini-gastric bypass and 1 sleeve gastrectomy. There were no complications reported during the dissection and anastomosis in our patients. 1 patient developed intra-operative hypotension. The complication rates during these surgeries were comparable to similar studies done by Holeczy et al <sup>[24]</sup> and Rassweiler et al <sup>[25]</sup>.

Over all among the 600 patients operated 13 (2.16%) had wound related complications. This was the most common complication among the study group and among all the sub groups. Analysis of risk factors for surgical site infection revealed that diabetes had a significant association with incidence of SSI with P value of <0.001 (Highly significant). Correlating the risk of anesthetic complications with ASA class and duration of surgery, we saw that ASA class I had no anesthetic complications reported, while 1 complication was reported in each of ASA class II and ASA class III. Prolonged surgery was also an added risk factor for anesthetic complication.

### Conflict of Interest: None

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