Original Research Article

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A study of venous thromboembolic complications following laparoscopic mesh hernioplasty for midline ventral hernias

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ABSTRACT

Background: Midline ventral hernia is a common complication of abdominal surgeries. Laparoscopic mesh hernioplasty is novel method of hernia repair but has many complications. Venous thromboembolic complications are one of them.

Methods: A prospective observational study in patients with midline ventral hernia was carried out. Based on the size of defect patients were divided into two groups (consisting 60 patients each). Group A with hernia defect size of less than 6cm and group B with more than 6 cm. Group A patients underwent intraperitoneal onlay mesh plus repair and group B patients underwent endoscopic components separation technique with intraperitoneal onlay mesh repair. Each patient was followed up at day 5 and day 30 postoperatively and Well's score was calculated. The patients with 'Likely' score were taken for Doppler ultrasonography. The patients with 'Unlikely' score were further evaluated with D-Dimer study. Patients with raised value of D-Dimer were taken for Doppler ultrasonography.

Results: Well's score on post-operative day 1 and 5 did not show any statistical significance between both groups (p<0.05). D-dimer done in Unlikely score showed no statistical significance. In all the patients with Likely score and raised D-dimer, no abnormality was detected on sonography.

Conclusions: Performing Wells score preoperatively and postoperatively one can get an idea about the risks of development of thromboembolic events.

Keywords: Ventral hernia, Endoscopic component separation, Venous thromboembolism, Pulmonary embolism

INTRODUCTION

Ventral hernia secondary to a previous abdominal surgeryis a common problem. Ventral hernia repair is a challenging operation commonly performed by general surgeons. Laparoscopic repair is now being preferred over open approach. However, laparoscopic repairs continue to be associated with many morbidities including pulmonary, gastrointestinal, cardiac complications and thromboembolic events. Venous thromboembolism (VTE) is an uncommon but a serious complication. A comprehensive scientific review by the

world thrombosis day (WTD) steering committee revealed that 10 million cases of VTE occur annually – across low, middle and high income countries.³ Yet, VTE-related death is largely undocumented with data predominantly confined to Europe and the United States. Certain factors and situations can increase the risk of developing potentially deadly blood clots and they may be due to family history of VTE, long period of hospitalization, prolonged period of surgery, delay in postoperative ambulation, orthopedic and cancer related surgeries, advanced age, medication, obesity, pregnancy, alcohol and smoking.

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Many different scores and diagnostic modalities are used to diagnose VTE and depend upon the severity of the clinical and biochemical parameters. Well's Risk Probability Score, D-dimer level and ultrasonography are the usual modalities used.4 Though VTE has been reported as a component of a gamut of complications of ventral hernia repair, there is lack of adequate data available on the association between the two. As of today, not a single prospective study is available that specifically addresses the association of VTE following midline ventral hernia repair. There is thus a need to assess the magnitude of the risk of VTE following laparoscopic mesh hernioplasty for ventral hernias and also to assess the risk in different types of mesh hernia repairs. The aim of this study is to observe the venous thromboembolic complications following laparoscopic mesh hernioplasty.

METHODS

A Prospective clinical observation studywas conducted from November 2018 to March 2020 at department of surgery, Lady Hardinge medical college and Dr. Ram Manohar Lohia hospital, New Delhi. A convenient sample size of 120 patients was included in the study. All adult patients with midline ventral hernia of age 18-80 years, who were fit to be operated under general anesthesia and had consented for the same were included in our study. We excluded the pregnant and lactating patients, patients having a stoma, with severe respiratory or cardiac co-morbidities (ASA: III- V), having active abdominal wall infection, sinus or fistula at hernia site related to any previous surgery and who have Likely Well's score. A written and informed consent was taken from all the patients.

Patients were divided into two groups based on the size of their transverse diameter. Group A: transverse hernia defect of size less than 6 cm in which intraperitoneal onlay mesh repair was done. Group B: transverse hernia defect of more than 6 cm in which endoscopic component separation and intraperitoneal meshplasty was done. Routine investigations for general assessment and anesthetic fitness were done. A pre-operative CECT abdomen was done in all patients to assess the size and location of defect. The VTE complications were assessed using Updated Well's risk probability predictive scoring (2003) for DVT and PE in all the patients. The Well's scoring was done 3 times. One before study and 2 times post operatively at day 5 and day 30. Preoperative Well's scoring is done to exclude the high-risk patient for developing thromboembolic complications based on Likely score. In all the included patients a graduated pneumatic compression stocking for DVT prophylaxis was given at the onset of surgery and no medical anticoagulation treatment was started.

Assessment of venous thromboembolism: In the postoperative period patients were evaluated by Well's score at day 5. Those who had a Likely score were straight away taken up for Doppler ultrasound study to confirm the diagnosis of VTE. Those who had Unlikely score had a D-Dimer study. The patients whose D-dimer study was positive, then were made to undergo Doppler Ultrasound study to confirm the diagnosis and when D-dimer study was negative VTE was ruled out. Patients who did not developed VTE in the postoperative period were again assessed with Well's score at one month follow up and the same procedure was followed. The patients were finally declared as positive or negative for VTE only after the outcome at one month. Statistical analysis of the acquired data was done. Results were expressed as either medians (with range) or mean±standard deviation (SD) and analyzed with univariate and multivariate analysis using SPSS 19 software. Continuous data was analyzed using Mann Whitney U test/t test as applicable and categorical data using Chi-square test. The level of significance α=0.05, and p<0.05 was considered statistically significant.

RESULTS

The age in the study group was uniformly spread amongst the different age groups. In Group A, 31-50 age group (56.60%) was comparable to Group B (60.00%).

Table1: Age distribution of the study group.

Age group	Gr	oup A	Gr	oup B	P value
(years)	N	%	N	%	r value
20-30	6	10.0	8	13.3	
31-40	14	23.3	18	30.0	
41-50	20	33.3	18	30.0	0.918
51-60	10	16.7	6	10.0	
61 and above	10	16.7	10	16.7	•

Table 2: BMI distribution of the study group.

BMI	Gr	oup A	Gr	oup B	P value
DIVII	N	%	N	%	r value
<18.5 (underweight)	0	0.0	0	0.0	
18.5-22.9 (normal)	14	23.3	12	20.0	0.512
23-24.9 (overweight)	14	23.3	8	13.3	
>25 (obese)	32	53.3	40	66.7	

Table 3: Incidence of different sites of hernia.

Site of defect	Gro	up A	Group B		
(EHS classification)	N	%	N	%	
M 2	10	16.7	4	6.7	
M 3	34	56.7	16	26.66	
M 4	16	26.7	28	46.66	
M 5	0	0.0	12	20.0	

The study of group A included 26 males and 34 females, whereas in group B there were 34 males and 26 females.

Table 4: OR time, ECS time and time taken for mesh placement.

Variables	Group A (IPOM)		Group B (ECST)		
	Mean	SD	Mean	SD	
Laparoscopic mesh time	108.37	30.86	116.37	24.01	
Endoscopic ecs time	-	-	52.17	9.71	
Total operative time	108.37	30.86	168.37	30.86	

Table 5: Post-operative complications.

Complications		Gro	oup A	Group B		P
Complications		N	%	N	%	value
SSI	0	58	96.7	56	93.3	0.554
331	1	2	3.3	4	6.7	0.334
Skin	0	60	100.0	58	96.7	0.313
Dehiscence	1	0	0.0	2	3.3	0.313
Skin Necrosis	0	60	100.0	60	100.0	NA
Hematoma	0	60	100.0	60	100.0	NA
Seroma	0	60	100.0	60	100.0	NA
Mesh Infection	0	60	100.0	60	100.0	NA

Predominance of female subjects in the group A was most likely due to incisional hernia occurring following tubal ligation. The predominance of male subjects in group B was most likely due to occurrence of incisional hernia following emergency exploratory laparotomy in road traffic accident victim and laparotomies performed in the emergency in unprepared patients needing larger incisions. A higher percentage of higher body mass index in patients of Group B could be due to the reluctance of these patients to exercise as the presence of a large hernia inconveniences the efforts to exercise. The presence of associated co-morbid conditions, alcohol intake and smoking are often incriminated in the risk of developing midline hernias. It appears after noting symptoms that larger the defect size more likely is associated symptoms like pain. The small size of the hernia limited it to the umbilical region in Group A, the larger size of the hernia defect resulted in the encroachment of the infraumbilical region in Group B. The transverse diameter of the Group A ranged from a minimum of 1.5cm to a maximum of 5.5 cm. The mean of the size of defect was 4.4cm with a standard deviation of 1.87. In Group B the transverse diameter ranged from a minimum of 6.5 cm to a maximum of 10.5 cm. The mean of the size of defect was 7.7 cm with a standard deviation of 1.81. Component Separation Index was calculated in all 60 patients in group B. The mean CSI was 0.1488±0.1457. The mean operating time (adhesiolysis and meshplasty) was

108.37±30.86 minutes in Group A and it was 168.37±30.862 minutes in Group B. In the Group B, total time was further subdivided to time taken to complete the endoscopic part (endoscopic component technique), and rest for the completion of the laparoscopic part (adhesiolysis and meshplasty). The mean time to complete the endoscopic part was 52.17±9.71minutes and time for laparoscopic mean part 116.53±24.01minutes. The time taken to complete the laparoscopic part in Group B was longer because these patients with larger defects had more intraperitoneal bowel to bowel adhesions, adhesions between the omentum and anterior abdominal wall which is statistically significant (p<0.0001). Fascial approximation was achieved all the 120 patients included in both the groups.

Composite mesh was used in all the patients. The size of the mesh was decided intra-operatively depending upon the original defect size. The breadth of the mesh was kept fixed at 15 cm in all the cases. This gave an overlap of 7.5 cm on either side of the midline. A margin of at least 5 cm was kept above and below the ends of the midline neo-linea alba. Length of hospital stay may be attributed to post-operative pain, and in our setup, patients are reluctant to get discharged till the time they are completely relieved of pain. All the patients with uneventful post-operative period were encouraged to mobilize from post-operative day 1 and chest physiotherapy was started at the same time. The mean length of hospital stay in our study was 2.43days in Group A and 4.23 days in Group B with a standard deviation of 0.817 and 1.006 in Group A and B respectively, with a range of 2 to 7 days. The mean duration of hospital stay of Group B patients was more than Group A patients due to prolong duration and more dissection in surgery which is statistically significant with p<0.001.

None of the patients in our study developed a postoperative recurrence during the said period of study. We experienced no mortality among our study cases in either group during the period of study. In group A, 6 patients on post-operative day 5 and 8 patients had Likely score at one month post-operatively. Whereas in group B, 8 patients had Likely score on day 5 and 12 patients at 1 month. Comparing the two groups there was no statistically significant at both day 5 (p=0.694) or at one month (p=0.497) between group A and group B. In Group A, 10 patients had raised D-dimer levels on post op day 5 and 44 patients had normal levels. Similarly, 12 patients had raised D-dimer at 1 month post-operatively and 40 had normal levels. On comparing the number of patients with raised D-dimer within the group A at day 5 with those at 1 month the p value was found to be 0.35 which is statistically non-significant. In group B, 12 patients had raised D-dimer levels on post op day 5 and 6 had raised D-dimer at 1 month post-operatively. On comparing the number of patients with raised D-dimer within the group B at day 5 with those at 1 month the pvalue was found to be 0.38 which is statistically non-significant. When group A and B was compared with each other the results were found to be statistically non-

significant (p=0.729 on day 5 and p=0.688 on day 30). Doppler ultrasound was done for further evaluation.

Table 6: Numbers and percentage data of all variables.

	Group							
Variables	A				В			
variables	Post-C	OP D5	Post-OP 1 mo	onth	Post-C	OP D5	Post-C	P 1 month
	N	%	N	%	N	%	N	%
Wells score	6/60	10	8/60	13.3	8/60	13.3	12/60	20.0
D-dimer	10/54	18.5	12/52	23.1	12/52	23.1	6/48	12.5
USG Doppler	0/16	0	0/20	0	0/20	0	0/18	0

Table 7: Two-level DVT Wells score.

Parameters	Points	Patient score
Clinical feature		
Active cancer (treatment ongoing, within 6 months, or palliative)	1	
Paralysis, paresis or recent plaster immobilization of the lower extremities	1	
Recently bedridden for 3 days or more or major surgery within 12 weeks requiring general or regional anesthesia	1	
Localized tenderness along the distribution of the deep venous system	1	
Entire leg swollen	1	
Calf swelling at least 3 cm larger than asymptomatic side	1	
Pitting oedema confined to the symptomatic leg	1	
Collateral superficial veins (non-varicose)	1	
Previously documented DVT	1	
An alternative diagnosis is at least as likely as DVT	-2	
Clinical probability simplified score		
DVT likely	2 points or more	
DVT unlikely	1 point or less	

In group A ultrasound was done in 16 patients. 6 of them had Likely score and 10 had raised D-Dimer. Similarly, after a period of 1 month ultrasound was done in 20 patients 8 of them had Likely score and 12 had raised D-Dimer. All these patients did not have any sonological abnormality suggestive of thromboembolism. Similarly, none of the patients in group B had abnormal ultrasound results.

DISCUSSION

Endoscopic component separation technique was developed with an aim to address the complications associated with open component technique especially the high rates of wound complications.⁵ It appears that men are likely to have bigger hernias as they are more often outdoors and prone to more accidents. Also, bigger the incision bigger is the hernia defect. A recent data from American college of surgeons national surgical quality improvement program shows that 60% of ventral hernia repair are performed on patients with body mass indexes above 30 kg/m.^{2,6} The various predisposing factors for the development of hernia include malnutrition, smoking, alcohol intake, diabetes mellitus, immunosuppressive

states and chronic lung diseases. In a systemic review and meta-analysis by Gronkjaer et al it was found that current smokers had an increased risk of developing post-operative complications (30%) compared with patients who have never smoked. Operating time is considered to be an important predictor in determining the overall outcome of the patient. Switzer et al in their systemic review and meta-analysis found out that the mean operating time was 260.9 minutes in doing endoscopic component separation.

Jensen et al reported in their study that 18% of cases undergoing ECS developed wound complications, the most common of which was surgical site infection.⁹. Azoury et al in their study reported total wound complication of 16% in patients who had undergone component separation surgery.¹⁰ Pain in the immediate post-operative period is quite common post hernia repair and may be attributed to the extensive tissue dissection and use of tackers for intra-peritoneal mesh fixation. There is short length of hospital stay because all the patients were encouraged to ambulate by post-operative day 1, orally allowed by post-operative day 2 and chest physiotherapy by post-operative day 2. This was

attributed to meticulous dissection during ECS, proper overlapping of the defect by the mesh and proper patient preparation and optimization in the pre-operative period there is no recurrence. VTE, which includes DVT and PE, is a major cause of morbidity and mortality among hospitalized patients.¹¹

Table 8: Two-level PE Wells score.

Parameters	Points	Patient score
Clinical feature		
Clinical signs and symptoms of DVT (minimum of leg swelling and pain with palpation of the deep veins)	3	
An alternative diagnosis is less likely than PE	3	
Heart rate > 100 beats per minute	1.5	
Immobilization for more than 3 days or surgery in the previous 4 weeks	1.5	
Previous DVT/PE	1.5	
Hemoptysis	1	
Malignancy (on treatment, treated in the last 6 months, or palliative)	1	
Clinical probability simplified scores		
PE likely	More than 4 p	oints
PE unlikely	4 points or les	SS

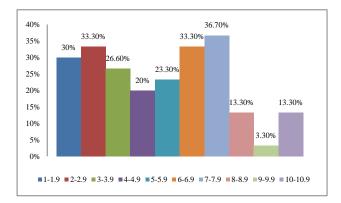


Figure 1: Size of defect (cm).

In the study conducted by Kim et al 2015, the rate of VTE was not significantly different between the non-component separation group and the component separation group suggesting that restoration of abdominal wall anatomy and physiology does not vary in terms of vascular compromise regardless of the type of repair.⁴ Thus, component separation can be performed with equal safety despite the challenging preoperative conditions and the stress of long and aggressive procedure

In a study conducted by Swaroopa et al have shown that the D-dimer test is highly sensitive (95%) in deep vein thrombosis and is marker of endogenous fibrinolysis with high negative predictive value. ¹² It is fast and costeffective way to triage patients with thromboembolic phenomenon. Although it has a high negative predictive value, patients with positive D-dimer undergo further imaging to determine whether or not they have VTE.

So, all in all, in spite of clinical and biochemical scrutiny, none of the patients developed radiological or clinical thromboembolic complications. But the abnormalities detected on Wells scoring and D-dimer estimation should not be ignored. To have better understanding

larger studies with larger sample size population, a longer time period and comparative randomized trials to further substantiate and validate our results and compare them with other hernia repair techniques should be undertaken.

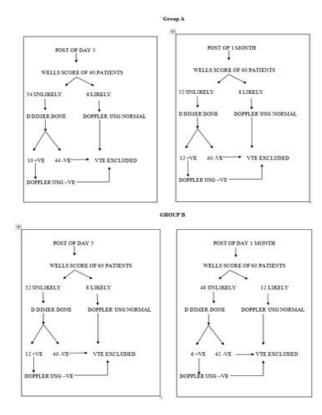


Figure 2: Algorithm showing postoperative follow up at day 5 and 30 of group A and B patients.

Limitations

We acknowledge that there are certain limitations of the study. This study was a prospective observational study and the patient selection was limited and non-randomized.

CONCLUSION

After analyzing the results, we found out that, in both the surgical techniques no case of venous thromboembolism was found. It is mainly because of gradual pneumatic compression applied at onset of surgery, early ambulation of patients in post-operative period and ruling out predisposing factors pre operatively. However, as the sample size was small it was not possible to reach any significant conclusion and whatever trend regarding adverse effects was suggested by the Scoring system and D-dimer studies it was not significant to show on radiological examination.

Recommendations

Both ECST and IPOM+ can be considered as ideal technique for midline hernia repair in patients of midline ventral hernia, especially the large defects. Performing Wells score preoperatively and postoperatively one can get a fairly good idea about the risks of development of thromboembolic events as it helps in further evaluation and investigations. This may help us in reducing these complications by applying necessary interventions such as stocking and early ambulation.

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Ethical approval: The study was approved by the

Institutional Ethics Committee

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