A Study to Find the Influence of Sterilization Protocol and Antibiotic Prophylaxis on Mesh Infection among Ventral Hernia Patients Repaired by Laparoscopy Technique – Prospective Study

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Abstract

Objective: In the modern practice of usage of laparoscopy to repair different types of Ventral Hernias (VHs). A study was conducted to evaluate Mesh Infection (MI) rate and other complications during VH repair with proper pre, intra-operative and post-operative protocol.

Methods: It was a prospective observational study, conducted in GMR Varalakshmi Care Hospital, from January 2015 to 2020. The study protocol was approved by the institutional Ethics committee. VH individuals with controlled glycemic status, aged 16years-70years, fit for General Anesthesia (GA). Proper preoperative, intraoperative, and post-operative care practices were followed. Along with routine antibiotic coverage, all the participants were on Azithromycin prophylaxis to prevent atypical mycobacterial infection. Gas Plasma sterilization (PS) was used for the sterilization of the surgical instruments. Change of gloves done for every case before handling mesh. The patients were discharged after 4 days. During this period, they were monitored thoroughly for complications. Simultaneously, they were asked to come for follow-up at regular intervals for 1 year. The complications were recorded and treated as per the protocol.

Results: A total 255 (100%) VH cases were included, and intermediate complications were identified in 1.56%. The rate of Late Complications (LCs) was 15 (5.88%). In LCs, seroma is the predominant (3.13%) followed by recurrence 6 (2.35%) and mesh infection 1 (0.39%).

Conclusion: Following proper sterilization protocol, antibiotic prophylaxis with Azithromycin, and practices such as a change of gloves before handling mesh can significantly reduce the rate of infection in VH patients those were repaired by laparoscopy technique.

Keywords: Ventral hernia • Laparoscopy • Infection

Introduction

Ventral Hernia (VH) is a defect in anterior abdominal wall. Incisional, umbilical epigastric, and Spigelian hernia are the different clinical presentations of VH. Different classifications of VH were reported in the literature [1]. These were according to location, size, recurrences, and based on symptoms (Figures 1-5).

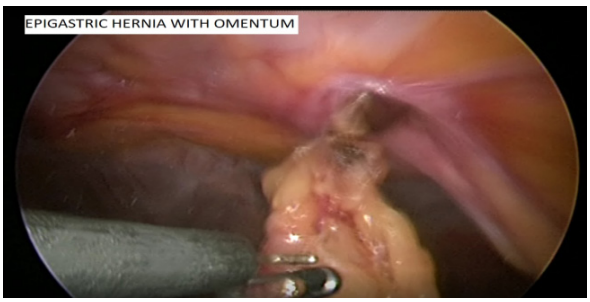

Figure 1. Epigastric hernia with omentum as content.

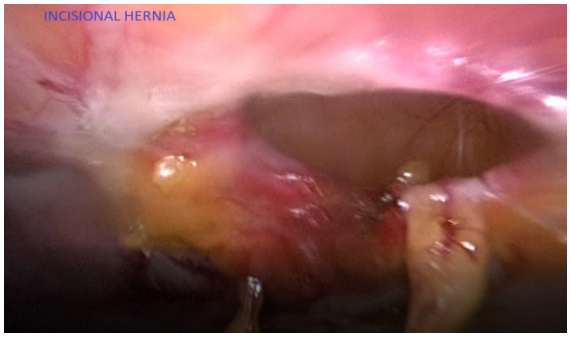

Figure 2. Incisional hernia defect.

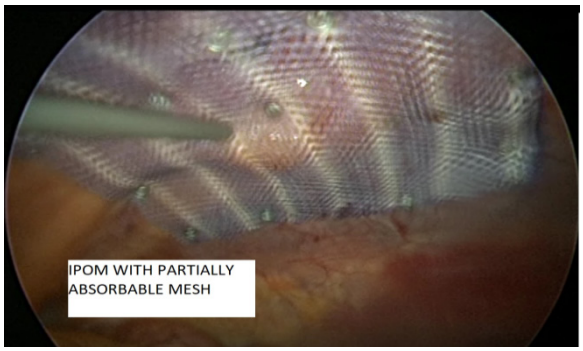

Figure 3. Laparoscopy hernia repair with mesh [IPOM].

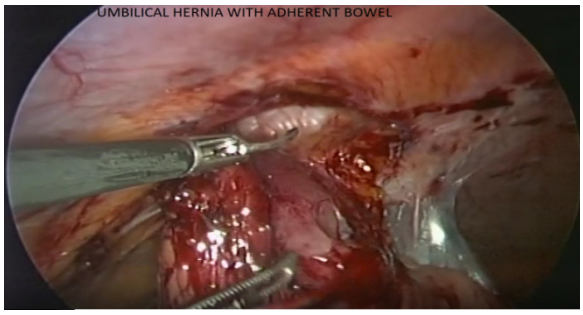

Figure 4. Umbilical hernia with adherent bowel.

Figure 5. Umbilical hernia with omentum as content.

With the growth in medical science, there is a significant change in the management of VH. Due to the complications associated with open repair and because of the introduction of the laparoscopy technique, there is a decrease in the management of VH using the open technique [2-4]. Leblanc and booth are the first to perform the laparoscopy technique of VH repair in 1993 [5]. Ease of the technique is another advantage of wide-stream utility.

The causes of ventral hernia can be congenital or acquired [6]. Congenital causes can be due to connective tissue disorders and acquired causes can be due to multiple factors; these include age, the weight of the patient, and operative as well as post-operative factors. Mesh is an important area of infection in VHs. In addition to improper surgical technique, antibiotic coverage as well as glycemic control, improper sterilization is the most important contributing factor Mesh Infections (MIs).

Atypical mycobacteria are frequently seen as the culprit. With this, a study was conducted on MI rate and other complications during laparoscopic VH repairs by following a standard protocol.

Materials and Methods

It was a prospective observational study, conducted in GMR Varalakshmi Care Hospital, Rajam, Andhra Pradesh. The study was conducted for a period of 5 years, January 2015 to 2020. The study protocol was approved by the institutional Ethics committee. Informed written consent was taken from all the participants.

VH individuals with controlled glycemic status, aged 16 years-70 years fit for General Anesthesia (GA) and who are non-emergency for surgery were included in this research. Those who are not fit for GA, aged<16 year and>70 years, pregnancy, emergency, uncontrolled diabetics with HbA1c>8, portal hypertension, coagulopathy, moderately obese with BMI, larger hernia defects of>8 cms, and those who refused to submit informed written consent were not considered.

Through and proper protocols were prepared namely preoperative preparation of the participants, standard intraoperative, and standard post-operative care. These were also approved by the concerned committee of this institution. Different sterilization techniques were reported in the literature [7,8]. As part of the preoperative study protocol, Gas Plasma Sterilization (PS) was used for sterilization of the surgical instruments. As we included nonemergency cases only if required, the study participants who were obese were asked to reduce their weight, stop smoking for 6 weeks prior to the surgery, and have good glycemic control among the diabetics prior to surgery (Figure 6).

All the participants were on Azithromycin Prophylaxis to prevent atypical mycobacterial infection. As part of the study's post-operative protocol, the patients were on antibiotic coverage for 3 days along with analgesics and discharged on the fourth postoperative day. During this period, they were monitored thoroughly for complications. Simultaneously, they were asked to come for follow-ups at regular intervals for a period of 1 year. The complications were recorded and treated as per the protocol.

Figure 6. Plasma sterilization machine in our institute.

Result

We conducted this study for a period of 5 years (for each case 1 year post-op follow-up). We did 255 surgeries under laparoscopy in all 5 years together after excluding some cases as per exclusion criteria. We monitored for intraoperative and postoperative complications in each case, Along with our primary interest i.e. Incidence of Mesh Infection [MI] and Seromas, we also monitored all other complications based on their time of occurrence into immediate and intermediate, and late complications as mentioned below. Incidence of mesh infections and incidence of seromas were monitored in both intermediate and late complications (Table 1).

In our study we didn't find any incidence of immediate complications which is 0% immediate complications. We described in detail in the following (Table 2).

We also monitored for incidence of all intermediate complications, apart from Port site infections we did not observe any other complications. There were 4 cases of port site infection (1.56%). We did not find any incidence of seromas in the intermediate phase, i.e. (0%) (we did not find a single case of seroma within 1-week post-operative period we also monitored the incidence of seromas in the late phase also).

We did not find the incidence of mesh infections within 1 week period postoperatively i.e. 0%. The incidence of mesh infections monitored in late phase is also described in detail in the following (Table 3).

We also observed and monitored the occurrence of late complications which was our primary intention of this study particularly mesh infections.

In our study overall incidence of Late Complications (LCs) was 5.88% (15 cases) in this research; in LCs, seroma was the predominant (8 cases; 3.13%) followed by recurrence (6cases; 2.35%) and MI (1case; 0.39%). Described in detail in the following (Tables 4-7). We did not find any case of seroma and mesh infection within 7 days of post-operative period, as mentioned in previous Table 3.

Table 1. Classification of complications of ventral hernia repairs.

Immediate[<24 hours]	Intermediate[1-7 days]	Late [after 7 days]
Bleeding	Seroma	Mesh infection
Bowel injury	Port site infection	Port site infection
	Mesh infections	Enterocutaneous fistula
		Seromas

Table 2. Incidence of various immediate complications year-wise.

Immediate Complications						
	2015	2016	2017	2018	2019	2020
Bleeding.	0[0%]	0[0%]	0[0%]	0[0%]	0[0%]	0[0%]
Bowel injury.	0[0%]	0[0%]	0[0%]	0[0%]	0[0%]	0[0%]
Total Cases	27	26	40	62	51	49

Table 3. Incidence of intermediate complications year wise.

Intermediate Complications						
	2015	2016	2017	2018	2019	2020
Port site Inf.	2[7.4%]	2[7.69%]	0[0%]	0[0%]	0[0%]	0[0%]
Seroma	0	0	0	0	0	0
Mesh infection	0	0	0	0	0	0
Total Cases	27	26	40	62	51	49

Table 4. Incidence of late complications.

Late Complications						
	2015	2016	2017	2018	2019	2020
Seroma.	2[7.4%]	1]3.84%]	1[2.5%]	1[0.62%]	2[3.9%]	1[2.04%]
Mesh Inf.	0 [0%]	1[3.84]	0[0%]	0[0%]	0[0%]	0[0%]
E.C Fistula.	0	0	0	0	0	0
Recurrence	1[3.07%]	1[3.84%]	1[2.%]	2[3.2]	1[1.96]	0[0%]
Total Cases	27	26	40	62	51	49

Table 5. Incidence of seromas in total study.

Total number of case done in last 5 years	Number of cases developed seromas	Seroma rate
255	8	3.137%

Table 6. Incidence of recurrence of hernia in total study.

Total number of cases done in 5 years	Number of cases of recurrence	Recurrence rate
255	6	2.35%

Table 7. Incidence of mesh infection in total study.

Total number of cases done under last 5 years	Number of cases with infected mesh	Mesh infection rate
255	1	0.39%

Discussion

It was a fact that VH repair using laparoscopy has several advantages; short operation as well as hospitalization time, recovery time is also very short so that the patient can return to work which can influence the financial statuses, lower rate of incidence of wound infections and complications.

The MI rate in this study was 0.39% (Table 5). It was a prospective study over a period of 5 years. With the long duration of the study period, less rate of infection is highly appreciable. There were several contributory factors for this. This is not a tertiary healthcare setup, so we don't have residents to train. All the interventions were carried out by a surgeon, the senior most. These two are the main contributory factors for a very less rate of MIs as there was no deviation of the study protocol. Other than the surgical issues, there are several patient factors such as smoking, glycemic status, obesity and so on that may lead to MIs [9,10]. As part of the study protocol, the study participants were thoroughly counselled regarding smoking and other aspects. MacKenzie Landin et al. conducted a prospective study on the effect of tobacco usage in the outcome of laparoscopy hernia repair; it was mentioned that 38.5% had a history of smoking and 18% are current smokers. Finally, the investigators concluded that if they failed to quit smoking prior to surgical repair can lead to associated complications as well as return to the operating room and statistically also there was a significant difference [11].

There was a prospective study report by Patrick Hamid Alizai et al. on the impact of obesity on postoperative complications after laparoscopic hernia repair; in this 39% of the study members were obese. The authors reported that the death rate was more among obese patients without any statistical significance; the recurrence rates as well as long-term hospital stay and prolonged duration of surgery didn't have statistically significant difference [12].

Plasma Sterilization (PS) is one of the new concepts of sterilization, for 2 decades. By oxidation principle, this can destroy the contaminants. In addition to this, it can work at a low temperature so that heat-sensitive items also can be sterilized and no reports of hazards especially among healthcare workers [13-17]. In spite of the high cost, PS is used in this study as a sterilization mode. It is well-known fact that proper sterilization can help to control infections. Adding to this, antibiotic prophylactic treatment is another breakthrough in this research. Indiscriminate use of antibiotics is one of the contributing factors of the spreading of drug resistance. All the surgical procedure were under the State And Central Government Welfare Schemes. The majority of the study participants were not economically sound. With this, if Antibiotic Prophylaxis (AP) is not carried out, leads to an economic burden on the patients because the postoperative infections may not be covered in the government scheme and also loss of work days. The use of Azithromycin in the prophylaxis is based on the occurrence of atypical mycobacteria as frequent offenders in mesh infection.

But, in the AP there is a controversy in the literature. Philipp Kirchhoff et al. reported that AP can't be justified among patients without any complications and undergoing laparoscopy VH repair [18]. As per the Ferdinand Kockerling et al. report, AP can be omitted to the patients without any complications [19]. However, AP is strongly recommended by Wong Alvin et al. [20].

Conclusion

Following proper sterilization protocol, antibiotic prophylaxis, and change of gloves before handling the mesh can significantly reduce the rate of infection in VH patients who were repaired using the laparoscopy technique.

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