

## Original Research Article

# Comparative study in healing process and complications inpatient undergoing ventral hernia mesh repair with and without the usage of collagen granules

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### ABSTRACT

**Background:** Ventral hernias are the second most common type of hernias accounting for 21 to 35% of all types of hernias. Collagen is defined as an endogenous substance that forms an important structural component in connective tissue. Collagen granules have an advantage with a reduction in inflammatory cells during healing resulting in decreased days of healing. This study is to compare the outcome of a patient with and without collagen granules usage during ventral hernia open mesh repair.

**Methods:** This prospective comparative study was done in 50 cases of ventral hernias admitted to the department of surgery in VMKV Medical College, Salem between periods of March 2018 to October 2019 were chosen for the study. The test group was treated with collagen granules and the control group was collagen granules not been used during ventral hernia mesh repair.

**Results:** Most common surgical approach used in ventral hernia is open mesh repair. The study shows a group of patients where collagen granules are used after mesh fixation has faster wound healing, reduced seroma, and hematoma collection, and reduced hospital stay, reduced infection compared to the group of patients who undergone non-collagen closure.

**Conclusions:** The study shows a group of patients where collagen granules are used after mesh fixation has faster wound healing, reduced seroma, and hematoma collection, and reduced hospital stay, reduced infection compared to the group of patients who underwent non-collagen closure.

**Keywords:** Epigastric hernia, Hypertension, Incisional hernia, Surgical site infection

### INTRODUCTION

Ventral hernias are the most common surgical problem. Incisional hernia accounts for 80% of all ventral hernia. The presence of a ventral hernia is itself, an indication for repair when no substantial comorbid conditions exist. Elective ventral and incisional hernia repair are undertaken largely to alleviate symptoms and to prevent hernia incarceration with subsequent strangulation of the intestine.<sup>1</sup> It is estimated that about 20% of all ventral

hernias result in incarceration, although the actual percentage is not known.<sup>2</sup> The field of hernia repair has evolved as a result of surgical innovation and has benefited significantly from technological improvements.<sup>3</sup> Tension-free repairs are one of the key concepts that have revolutionized hernia surgery.<sup>4</sup> The use of mesh prosthesis to approximate the fascial defect has resulted in a decrease in recurrence rates for ventral and incisional hernias.<sup>5</sup> More recently, laparoscopic approaches to the ventral and incisional hernia have

extended the options and approaches for repairing the fascial defect.<sup>6</sup> Reconstruction of the abdominal wall to repair incisional hernias continues to pose a challenge for the surgeon, due to the lack of universally accepted technique for the repair with low recurrence and complication rates.<sup>7</sup> Poor surgical technique, repair under tension, topical contamination, and inadequate blood supply are the major risk factors for high recurrence rates.<sup>8</sup>

## METHODS

This prospective comparative study was done in 50 cases of ventral hernias admitted to the department of surgery in VMKV Medical College, Salem between periods of March 2018 to October 2019 were chosen for the study. The test group was treated with collagen granules and the control group was collagen granules not been used during ventral hernia mesh repair. The test group was treated with collagen granules and the control group was collagen granules not been used after ventral hernia mesh repair. Data were collected according to proforma which included a detailed history, clinical examination, and investigation. Data were tabulated, analyzed and results interpreted.

### *Inclusion criteria*

All cases were presenting with features of large ventral hernia and recurrent ventral hernia in the general surgery ward.

### *Exclusion criteria*

Exclusion criteria were inguinal hernia, ascites, DM, immunocompromised state/malignancy, hypoalbuminemia, anemia, obesity.

All patients underwent the following investigations. Blood glucose and urea, Serum creatinine, complete blood count, urine routine examination, X-ray chest PA view, ECG, Xray abdomen erect, or lateral decubitus view if needed, Ultrasonogram abdomen and pelvis, CT/MRI (if needed). As clinical diagnosis was made, patients with medical illness were appropriately treated to attain near-normal parameters before surgery at the induction of anesthesia, a prophylactic single dose of antibiotic (3rd generation cephalosporin) was given. Patients were assigned to undergo open mesh repair. Operative procedure: anaesthesia- GA/SA according to patient condition, position- supine, under SAP, and in the supine position, patient painted, and draped. The incision is made according to the type and size of the hernia. Incision deepened, defect, and sac identified, sac opened, content reduced. The defect is closed with primary suturing. Prolene mesh was used with at least 4 cm of mesh overlapping the edges of the fascial defect and secured with no. 1 prolene interrupted stitches over the fascia. Collagen granules are sprinkled over the mesh. Drain kept in situ in a controlled group in selected

patients based on defect size and not used in the test group. The incision closed in layers. Sterile dressing applied. Plan to stay in the hospital for 7 to 10 days after surgery (for open repair operations). Depending on the complexity of your hernia, may spend the first 1 to 2 nights in the ICU. pt was mobilized and started on an incentive spirometer. This device helps to take long, deep breaths to keep your lungs clear and active during your recovery period. For the first three to four days after surgery, the pain will be managed either by an intravenous (opioid group of drug or paracetamol infusion) or through an epidural catheter. Pain medicine is switched to an oral narcotic when patients can eat solid food. Pain scores are recorded in every patient using a pain scale. Continuous aspiration of suction drains is used to remove fluid buildup around the operative site. The length of time they need to remain in place varies based on where the drains need to be positioned, the type and location of mesh used, and the amount of fluid exiting into the drain. Some drains can be removed before hospital discharge; others may need to remain in place for about 2 weeks. Medication to prevent blood clots was started in the operating room and must continue to be taken until discharge. Antibiotics to prevent infection were started before surgery and will be stopped within 3-5 days. If the patient had a soft tissue or mesh infection before surgery, antibiotics will continue until the infection has resolved. The expected recovery period is 6 to 8 weeks after major abdominal wall reconstruction hernia surgery.

### *Statistical analysis*

Data entry was made in the Microsoft excel software in codes and analysis was done with an SPSS-20 computer package. Categorical variables are expressed as percentages whereas continuous variables are expressed as mean±standard deviation. Association between the categorical variable was found by the chi-square test and the relationship between the continuous variable was assessed by student's t-test. P value<0.05 was considered as statistically significant.

## RESULTS

Table 1 shows a total of 50 patients who underwent surgery for hernia were taken up for the study. Among these participants 25 were controls and 25 belonged to the test group. The majority of the participants were aged between 35 to 50 years (48%) and were females (56%). Among the various co-morbidities analyzed hypertension was the most prevalent co-morbidity present among 36% of participants.

Table 2 shows the group-wise characteristics of the study participants were analyzed according to the background characteristics. While the majority of the participants in the test group belonged to the age group was 50 to 65 years among the controls, they were 35 to 50 years. Similarly, while males are more common in the test

group while females predominantly were present in the control group. Both the groups had similar characteristics in terms of diagnosis being umbilical and para-umbilical hernia.

Table 3 shows among the various complications analyzed site infection was prevalent in 20% of the participants. There was wound dehiscence present in 10% of the participants and according to the pain classification majority of the participants reported a moderate level of pain (88%).

Table 4 shows overall 30 participants had a defect size of >3 MMS in the majority of the participant. The association between various complications among the test and control groups were analyzed. It was observed that site infection was present only in one participant in the test group compared to 9 participants in the control group (36%) the association was statistically significant ( $p < 0.005$ ).

**Table 1: Age wise distribution of hernia concerning sex**

Age (years)	Male		Female		Total	
	No. of patients	Percentage	No. of patients	Percentage	No. of patients	Percentage
<35	2	9.1	4	14.3	6	12
35-50	10	45.5	14	50	24	48
50-65	8	36.4	8	28.6	16	32
>65	2	9.1	2	7.1	4	8
<b>Total</b>	<b>22</b>	<b>44</b>	<b>28</b>	<b>56</b>	<b>50</b>	<b>100</b>

**Table 2: Group wise characteristics**

S. no.	Characteristics	Test (n=25) N (%)	Control (n=25) N (%)
1.	<b>Age (in years)</b>		
	<35	0(0)	6(24)
	35-50	10(40.0)	14(56)
	50-65	14(56)	2(8)
	>65	1(4.0)	3(12)
2.	<b>Sex</b>		
	Male	14(56)	8(32)
	Female	11(44)	17(68)
3.	<b>Diagnosis</b>		
	Epigastric hernia	4 (16)	5 (20)
	Incision hernia	6 (24)	5 (20)
	Umbilical and paraumbilical hernia	15 (60)	15 (60)
4.	<b>Co-morbidities</b>		
	Hypertension	11 (44)	7 (28)
	Coronary Artery Disease	5 (20)	2 (8)
	Bronchial Asthma	3 (12)	0 (0)
	Nil	6 (24)	16 (64)

**Table 3: Complications of surgery**

S. no.	Complications	Frequency (n=50)	Percentage (%)
1.	<b>Site Infection</b>		
	Yes	10	20
	No	40	80
2.	<b>Seroma</b>		
	Yes	22	44
	No	28	56
3.	<b>Hematoma</b>		
	Yes	2	4
	No	48	96
4.	<b>Wound healing</b>		
	Good	25	50
	Poor	25	50

Continued.

S. no.	Complications	Frequency (n=50)	Percentage (%)
5.	<b>Wound dehiscence</b>		
	Yes	5	10
	No	45	90
6.	<b>Recurrence</b>		
	Yes	1	2
	No	49	98
7.	<b>Pain Scale</b>		
	Mild	3	6
	Moderate	44	88
	Severe	3	6

Table 4 shows overall 30 participants had a defect size of >3 MMS in the majority of the participant. The association between various complications among the test and control groups were analyzed. It was observed that site infection was present only in one participant in the test group compared to 9 participants in the control group (36%) the association was statistically significant (p value < 0.005).

Table 5 As far as seroma was concerned, seroma was present in 20% of the test group participants whereas it was present in 68% of the control group participants (p value < 0.001). Table 6 shows hematoma among the study participants was also analyzed. Although none of the

participants had a hematoma in the test group 2 participants (8%) had a hematoma in the control group. However, the association was not statistically significant.

Table 7 wound healing was better in the test group (76%) compare to the control group. (24%) the observed difference was statistically significant (P value < 0.0001).

**Table 4: Defect size (n=50).**

Defect size	Frequency	Percentage (%)
<3 mm	10	20
>3 mm	40	80

**Table 5: Association between outcomes and study groups– seroma.**

S. no.	Seroma	Test N (%)	Control N (%)	Chi-square test	P value
1.	Yes	5(20)	17(68)	11.6	0.001
2.	No	20(80)	8(32)		

**Table 6: Association between outcomes and study groups – hematoma.**

S. no.	Hematoma	Test N (%)	Control N (%)	Chi-square test	P value
1.	Yes	0(0)	2(8)	2.08	0.149
2.	No	25(100)	23(92)		

**Table 7: Association between outcomes and study groups –wound healing.**

S. no.	Wound healing	Test N (%)	Control N (%)	Chi-square test	P value
1.	Good	19 (76)	6 (24)	13.5	0.0001
2.	Poor	6 (2)	19 (76)		

**Table 8: Association between outcomes and study groups – wound dehiscence.**

S. no.	Wound dehiscence	Test N (%)	Control N (%)	Chi-square test	P value
1.	Yes	0(0)	5(20)	5.56	0.018
2.	No	25(100)	20(80)		

**Table 9: Association between outcomes and study groups – recurrence.**

S. no.	Recurrence	Test N(%)	Control N(%)	Chi-square test	P value
1.	Yes	0(0)	1(4)	1.02	0.312
2.	No	25(100)	24(96)		

**Table 10: Association between outcomes and study groups – duration of hospital stay.**

S. no.	Duration of surgery	Test N(%)	Control N(%)	Chi-square test	P value
1.	5-10	23 (92)	8 (32)	19.1	0.0001
2.	>10	2 (8)	17 (68)		

Table 8 shows wound dehiscence was although nil in the test group and was present in 5 participants in the control groups. (20%) the observed difference was statistically significant (p value<0.05).

Table 9 recurrence of hernia was absent in the test group while the present in 1 participant in the control group. The observed difference was not statistically significant

Table 10 on comparing the duration of hospitalization it was observed that the test groups' majority of the participants were hospitalized for the period between 5 to 10 days among the control group (92%) compare to the test groups (32%) the observed difference was statistically significant (p value<0.0001).

## DISCUSSION

Ventral hernias are a familiar surgical problem. Ventral hernias include Incisional and primary defects in the abdominal fascia, which can cause umbilical, epigastric, or Spigelian hernias. There are various surgical techniques for ventral hernia, laparoscopic vs open repair is available with the use of prosthetic mesh which decreases recurrence rate.<sup>9</sup> But immediate complications with laparoscopic or open mesh repair are seroma, hematoma, infection, postoperative pain, delayed wound healing, wound dehiscence, mesh infection, etc which increases hospital stay and delays recovery period.<sup>10</sup>

Collagen is defined as an endogenous substance that forms an important structural component in connective tissue. The importance of collagen in healing has been appreciated for many decades for the reason that, Collagen granules have an advantage with a reduction in inflammatory cells during healing resulting in decreased days of healing.<sup>11</sup> Another advantage in terms of reduces post-op infection reduces seroma collection. The majority of the participants were aged between 35 to 50 years (48%) and were females (56%). Koehler al identified the patients with incisional hernia were between 25 to 90 years and mean age of 60.3 years. In our study, most of them are the 4th and 5th decade of life because of the predominance of a female patient who underwent surgery for childbirth.<sup>12</sup> Hobar PC et al found the male to female ratio is 1:5 in his study. The group-wise characteristics of the study participants were analyzed. While the majority of the participants in the test group belonged to the age group was 50 to 65 years among the controls, they were 35 to 50 years. Similarly, while males are more common in the test group while females predominantly were present in the control group. Both the groups had similar

characteristics in terms of diagnosis being umbilical and para-umbilical hernia. The female patient had a higher incidence of incisional hernia because of repeated pregnancy causing laxity of abdominal wall and obesity which caused infection post-operatively.<sup>13</sup> Lang et al reported that previous surgery had been complicated by post-operative wound infection in 48.8% of developed hernia. Larson et al reported 35.9% and Bose had 53.6%. Certainly, Incisional hernia is not unique to elderly patients but wound healing is somewhat impaired in patients older than 60 yrs of age and the incidence of the incomparable situation is considerably increased with tissues.<sup>14</sup> Anemia, diabetes mellitus, obesity, alcoholism, smoking has been associated with a high percentage of post-operative hernias. Among the various co-morbidities analyzed hypertension was the most prevalent co-morbidity present among 36% of participants obesity has been cited as a risk factor for acute fascial dehiscence and incisional hernia after major abdominal operations.<sup>15</sup>

The size of the fascial defect and the appearance of fascia should dictate the selection of the most appropriate method of hernia repair. Wound infection is the major cause of postoperative herniation having a high propensity for fascial necrosis with resultant loss of integrity of the closure.<sup>16</sup> Sepsis is the second major cause of early wound failure in more than 50% of the postoperative hernias that develop in 1st year of operation. Approximately 35 to 40% of Incisional hernias occur with a documented history of wound infection but reported incidence of hernia treated wound infection varies from 5 to 20%.<sup>17</sup>

Postoperative wound infection was associated with a fivefold increase in the risk of development of hernia (23%) compared with patients with uninfected wounds (4.5%). Similar findings had been reported earlier by Muschaweck et al.<sup>18</sup> Among the various complications analyzed surgical site infection was prevalent in 20% of the participants. There was wound dehiscence present in 10% of the participants and according to the pain classification majority of the participants reported a moderate level of pain (88%). Overall, 30 participants had a defect size of >3 MMS in the majority of the participant.

The association between various complications among the test and control groups were analyzed.<sup>19</sup> It was observed that site infection was present only in one participant in the test group compared to 9 participants in the control group (36%) the association was statistically significant (p value<0.005).<sup>20</sup> As far as seroma was

concerned, seroma was present in 20% of the test group participants whereas it was present in 68% of the test group participants ( $p$  value $<0.001$ ). Hematoma among the study participants was also analyzed.<sup>21</sup> Although none of the participants had a hematoma in the test group 2 participants (8%) had a hematoma in the control group. However, the association was not statistically significant.<sup>22</sup> Wound healing was better in the test group (76%) compare to the control group. (24%) the observed difference was statistically significant ( $p$  value $<0.0001$ ).

Wound dehiscence was although nil in the test group and was present in 5 participants in the control groups. (20%) the observed difference was statistically significant ( $p$  value $<0.05$ ).<sup>23</sup> Recurrence of hernia was absent in the test group while the present in 1 participant in the control group. The observed difference was not statistically significant.

On comparing the duration of hospitalization it was observed that the test groups' majority of the participants were hospitalized for the period between 5 to 10 days among the control group (92%) compare to the test groups (32%) the observed difference was statistically significant ( $p$  value $<0.0001$ ).<sup>24</sup> Collagen granules are effective in hastening the healing process by reducing the inflammatory process as complications like seroma collection, infection and pain are minimal or absent and reduced hospital stay, postoperative complications are reduced compared to non-collagen closure.<sup>25</sup>

### Limitations

Limitation of the study is that there were only clean cases examined. Therefore, it is not possible to conclude whether the results will be the same in a contaminated case. However, since there are no prior animal model studies using porcine hepatic mesh for repair of ventral hernias, it is prudent to evaluate the mesh in a clean setting before introducing confounding factors such as contamination. Futures studies evaluating the outcomes of porcine hepatic meshes in contaminated surgical fields are needed.

### CONCLUSION

Most of the ventral hernias except congenital varieties are presented in the 3rd to 7th decades. 90% of ventral hernias were uncomplicated at the time of presentation, the remaining 10% presented with either obstruction or strangulation necessitating emergency repair. Mesh repair is the technique of choice for most incisional hernias and all ventral hernias with any size of the defect. Though sub lay/underlay mesh placement is more physiological, it can be placed either inlay or onlay. The study shows a group of patients where collagen granules are used after mesh fixation has faster wound healing, reduced seroma, and hematoma collection, and reduced hospital stay, reduced infection compared to the group of patients who underwent noncollagen closure. Collagen granules are

effective in hastening the healing process by reducing the inflammatory process as complications like seroma collection, infection is minimal or absent, and reduced hospital stay, postoperative complications are reduced compared to non-collagen closure.

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