Outcome of inlay ventralex hernia patch among patients with ventral hernia at Zagazig University Hospitals, Egypt

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Background
Multiple techniques have been clarified for mesh placement in the hernia repair surgery, including onlay, sublay, and inlay positioning. Meshes with a dual layer have been developed to prevent the formation of adhesions of the viscera to the intraperitoneal mesh. So, the present investigation was conducted to compare the outcome of the ventral hernia repair using inlay ventralex hernia patch with the classic onlay prolene mesh.

Patients and method
s A randomized clinical trial was carried on 60 patients with a ventral hernia in the Department of General Surgery, Zagazig University Hospitals, Egypt, from January 2018 to January 2020. The patients were equally divided into two groups: group A with inlay ventralex hernia patch and group B with onlay prolene mesh.

Results
Regarding demographics and clinical presentation, no statistically difference was found between both groups, whereas there was a highly significant differences between group A and group B in the operative time, with mean of 35.4±0.25 and 50.2±0.14 min, respectively, with no significant difference between them in anesthesia type, defect size, and mesh size. On comparing the postoperative complications, a significant difference was found between them regarding wound seroma, wound infection, and postoperative pain. Moreover, a highly significant shorter hospital stay, time of return to work or normal activity, and mean postoperative follow-up were observed in group A.

Conclusion
The inlay ventralex hernia patch is an effective and easier technique and can also save the operative time with less postoperative complications and better outcomes as compared with the classic onlay prolene mesh. So, its use is considered cost-effective.

Keywords:
hernia, inlay patch, onlay mesh

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Introduction

Abdominal wall hernias are still a common surgical challenge. Repair of the ventral hernia remains a common operation performed by the surgeons nowadays [1]. Ventral hernias represent 10–15% of all primary hernias and include umbilical, epigastric, and incisional hernias [2].

Many surgeons recommend surgical repair of the ventral hernias to avoid the potential risk of incarceration and strangulation [3].

Primarily suture closure was used to repair the epigastric and umbilical hernias. High recurrence rates (10–30%) were found for umbilical hernia closure using traditional suture repair or Mayo techniques [4].

Several studies have reported the efficacy of mesh hernioplasty versus suture repair for the small midline hernias of 1–3 cm [5,6].

Multiple techniques were clarified for mesh placement in hernia repair surgery including onlay, sublay, and inlay [7]. Meshes with a dual layer have been developed to avoid the formation of adhesions of the viscera to the intraperitoneal mesh [8].

The ventralex hernia patch is a self-expanding, nonabsorbable, and circular bilayer prosthesis that consists of an outer polypropylene monofilament mesh and an inner expanded polytetrafluoroethylene (ePTFE) surface [9].

So such patches are suitable for the small ventral hernias owing to less dissection, but the risk of recurrence and complications of these patches

compared with onlay mesh placement are still unclear [10].

Therefore, the current investigation was carried out to compare the outcome of the ventral hernia repair (operative time, wound infection, hospital stay, postoperative pain, and recurrence) using inlay ventralex hernia patch with the onlay prolene mesh.

Patients and methods

Study design and setting

A randomized clinical trial was done during the period from January 2018 till January 2020 in the Department of General Surgery, Zagazig University Hospitals, Egypt.

Study population

Inclusion criteria

The following were the inclusion criteria:

(1) Patients with the ventral hernia defect equal to or less than 3 cm.
(2) Patients with age equal to or more than 18 years old.
(3) Both sexes were included.

Exclusion criteria

The following were the exclusion criteria:

(1) Patients with a strangulated, irreducible, or inflamed hernia.
(2) Pregnancy or patients with bleeding tendency history.
(3) Inability to cooperate with the requirement of the study.

Sampling

A total of 60 patients presented with primary ventral hernia were involved in the investigation and categorized into two groups: group A included 30 patients with inlay ventralex hernia patch and group B had 30 patients with onlay prolene mesh. The selection was done by a systematic random sampling technique.

Study tools

All patients underwent the following:

(1) Full history: personal history (name, age, sex, residence, admission date, telephone number, and other habits of medical interest) and past history (medical and surgical).
(2) Full clinical assessment: symptoms (such as see and feel any bulge protrude in the abdomen during cough or strain), signs (such as the defect site and size), and digital rectal examination.
(3) Investigations: routine preoperative studies such as complete blood count, coagulation profile, kidney and liver functional tests, random blood sugar, ECG, and imaging studies (abdominal ultrasound and chest radiography).

Study method

Patient preparation

The patient was kept nothing by mouth (NPO) before the operation for 6 h. Prophylactic antibiotics (intravenous 1 g of Cefotax) were given with the anesthesia induction. All selected patients were fit for surgery and anesthesia.

Operative techniques

Under general or spinal anesthesia, operations were carried out with the patient in the supine position.

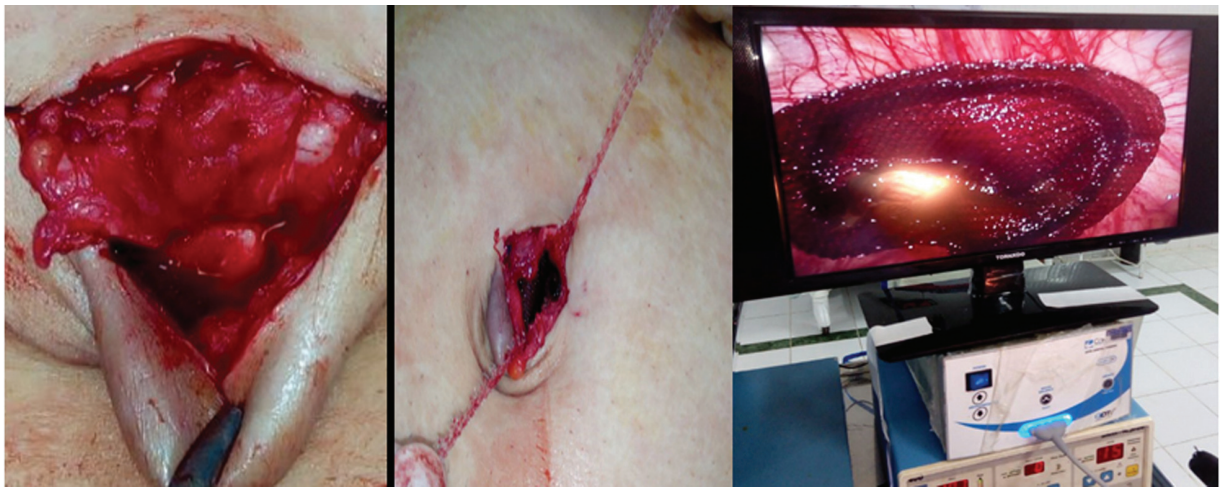
Group A: the skin was incised transversely over hernia. The hernia sac was dissected out, opened, and excised if necessary after reduction of its contents. The mesh size depends on the defect size to ensure overlap of the defect at least 2.5 cm on all sides. The hernia patch was inserted through the defect and positioned intraperitoneally, and the straps were secured onto the defect edges with 2–4 interrupted 2/0 Prolene (Ethicon, Cincinnati, Ohio, USA). The patch thereby flattens against the underside of the abdominal wall. Fascia defect was then approximated anteriorly using interrupted sutures of 1-PDS (polydioxanone suture) (Fig. 1). The skin was closed with subcuticular stitches.

Group B: the skin is incised transversely over the hernia. Subcutaneous dissection was done to expose the fascia and the neck of the sac. Any protruding bowel was returned to the peritoneal cavity and removed the whole sac. The dissection was extended laterally to 5 cm around the hernial defect and then closure of the hernial defect was done with prolene 1 (Ethicon) sutures, followed by fixation of the mesh by 2/0 prolene (Ethicon) sutures (Fig. 2). The skin was closed with subcuticular stitches.

Postoperative care and follow-up

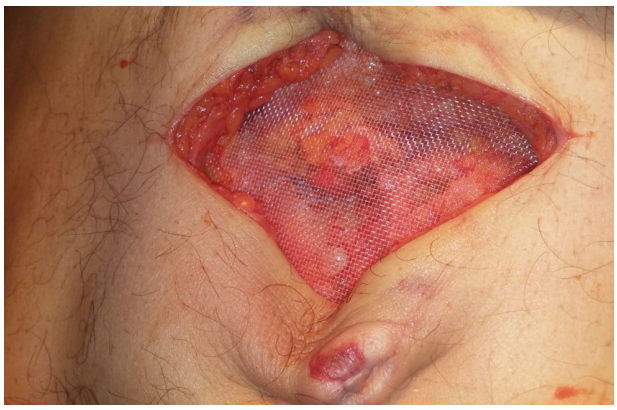
Antibiotics were continued postoperatively for 1 week. The patients were discharged within 24 h after the operation. Postoperatively, the patients were made ambulatory the day after surgery. Normal activity was permitted a week after instructions on discharge included

Figure 1



Hernia repair with the inlay ventralex hernia patch.

Figure 2



Hernia repair with the onlay prolene mesh.

avoidance of straining or carrying heavy objects for the following three months.

Follow-up visits were scheduled on fifth, seventh, and 14th day, and then at 3 months, 6 months, and annually for assessment of chronic pain, sinus formation, and hernia recurrence.

Ethics approval and consent to participate

Official permissions were attained from the Institutional Review Board at the Faculty of Medicine, Zagazig University Hospitals, and from the General Surgery Department at the same University. A written informed consent was taken from all patients. Furthermore, they had the right to withdraw from the investigation at any time and without negatively affecting their medical care. The results of the present study could be used as a scientific publication, but the identity of the participant will be absolutely confidential.

Statistical analysis

All statistical calculations were done using computer program IBM SPSS (Statistical Package for the Social Science; IBM Corp, Armonk, NY, USA) version 20 for Microsoft Windows. Quantitative data were expressed as mean±SD and qualitative data were presented as number and percentage. χ^2 test and Fisher exact test were performed to analyze qualitative variables, whereas an independent *t*-test was performed to analyze continuous data. The results were considered statistically significant and highly statistically significant when the *P*value was less than 0.05* and less than 0.001**, respectively.

Results

A total of 60 patients with primary ventral hernia were involved and divided into 30 patients in group A (inlay ventralex hernia patch) and 30 patients with patients in group B (onlay prolene mesh), with no statistically significant difference ($P \geq 0.05$) between them concerning demographic (age and sex) and clinical presentation (BMI and type of hernia), ensuring comparability of both groups. The mean age of group A was 47.7±9.8 years, whereas the mean age for group B was 45.1±10.3 years. More than half of both the groups were females, with mean BMI of 32.6 ±0.66 and 32.2±0.97 kg/m^2 in group A and group B, respectively. Paraumbilical hernia (PUH), epigastric, umbilical, incisional, and port site hernias were the types of hernia involved in this study, and the most common type was PUH in both group A and group B, with percent of 56.7 and 50%, respectively (Table 1).

Regarding the intraoperative characteristics, there was a highly statistically significant differences ($P<0.001$**)

Table 1 Demographic and clinical presentation of the studied groups (*n*=60)

Characteristics	Group A (*n*=30) [*n* (%)]	Group B (*n*=30) [*n* (%)]	*P* value
Age (years) (mean±SD)	47.7±9.8	45.1±10.3	0.326[a]
Sex			
Female	18 (60)	16 (53)	0.602[b]
Male	12 (40)	14 (47)	
BMI (kg/m^2) (mean±SD)	32.6±0.66	32.2±0.97	0.109[a]
Type of hernia			
PUH	17 (56.7)	15 (50)	0.934[b]
Epigastric	6 (20)	9 (30)	
Umbilical	5 (16.7)	4 (13.4)	
Incisional	1 (3.3)	1 (3.3)	
Port site hernia	1 (3.3)	1 (3.3)	

PUH, para umbilical hernia. [a]Independent *t*-test. χ^2 test.

Table 2 Intraoperative characteristics of the studied groups (*n*=60)

Characteristics	Group A (*n*=30) [*n* (%)]	Group B (*n*=30) [*n* (%)]	*P* value
Type of anesthesia			
General	20 (66.7)	18 (60)	0.592[a]
Spinal	10 (33.3)	12 (40)	
Operative time (min) (mean±SD)	35.4±0.25	50.2±0.14	<0.001**,b
Defect size			
<2 cm	22 (73.3)	19 (63.3)	0.405[a]
<3 cm	8 (26.7)	11 (36.7)	
Mesh size			
Small-size mesh	22 (73.3)	19 (63.3)	0.405[a]
Medium size mesh	8 (26.7)	11 (36.7)	

[a]χ^2 test. [b]Independent *t* test. **Highly significant ($P<0.001$).

Table 3 Postoperative complications among the studied groups (*n*=60)

Complications	Group A (*n*=30) [*n* (%)]	Group B (*n*=30) [*n* (%)]	*P* value
Wound seroma			
Yes	1 (3.3)	7 (23.3)	0.022*,a
No	29 (96.7)	23 (76.7)	
Wound infection			
Yes	1 (3.3)	6 (20)	0.044*,a
No	29 (96.7)	24 (80)	
Postoperative pain			
Yes	1 (3.3)	6 (20)	0.044*,a
No	29 (96.7)	24 (80)	
First postoperative day VAS score (mean±SD)	4.4±0.16	5.07±1.1	0.002*,b
Recurrence			
Yes	1 (3.3)	2 (6.7)	0.554[a]
No	29 (96.7)	28 (93.3)	

VAS, visual analog scale. [a]Fisher exact test. [b]Independent t test. *Significant ($P<0.05$).

between group A and group B in operative time, with mean of 35.4±0.25 and 50.2±0.14 min, respectively. However, there were no significant differences ($P\geq0.05$) between them regarding the type of anesthesia, defect size, and mesh size where more than two-third of them had general anesthesia, defect size less than 2 cm, and small-size mesh (Table 2).

On comparing the postoperative complications, a significant statistically difference ($P<0.05$*) was found between group A and group B regarding wound seroma (3.3 vs 23.3%), wound infection (3.3 vs 20%), postoperative pain (3.3 vs 20%), and first postoperative day visual analog scale (VAS) score (4.4 ±0.16 vs 5.07±1.1), with no significant statistically difference ($P\geq0.05$) in recurrence (3.3 vs 6.7%) (Table 3).

The outcomes of both techniques in Table 4 clarified that there was a highly statistically significant shorter ($P<0.001$**) hospital stay, time of return to work or

Table 4 Outcome among the studied groups (*n*=60)

Outcomes	Group A (*n*=30)	Group B (*n*=30)	*P* value
Hospital stay (h)			
Mean±SD	20.04±0.11	26.12±0.12	<0.001**,a
Return to work or normal activity (days)			
Mean±SD	7.60±0.13	11.37±2.62	<0.001**,a
Mean postoperative follow-up (months)			
Mean±SD	16.00±0.09	24.05±0.15	<0.001**,a

[a]Independent *t*-test. **Highly significant ($P<0.001$).

normal activity, and mean postoperative follow-up in group A when compared with group B.

Discussion

Multiple studies were described that the repairing of mesh of the ventral hernias has minimized the complexity and frequency rates significantly [11,12]. Moreover, the mesh repairing is generally means a more extensive dissection that might higher the morbidity [13].

The avoidance of the extraperitoneal or prefascial dissection is considered one of the most advantage of the intraperitoneal placement of a mesh, thereby decreasing the complications rate and the need for wound drainage [7].

Regarding demographics and clinical presentation of the included groups in the present investigation, no statistically significant difference ($P\geq0.05$) was found between them, with a mean age in group A of 47.7±9.8 years, whereas the mean age for Group B was 45.1 ±10.3 years. More than half of them were females, with mean BMI of 32.6±0.66 and 32.2±0.97 kg/m^2 in group A and group B, respectively. PUH, epigastric, umbilical, incisional, and port site hernias were the types of hernia involved in this study and the PUH was the most common type in both group A and group B, with percent of 56.7 and 50%, respectively.

Similarly, the study conducted by Hadi *et al.* [14] found that 44 from all included patients had umbilical/PUH, five with epigastric hernias, one with midline incisional hernia, and one with port site hernia.

Vychnevskaia *et al.* [15] also demonstrated that the majority of their participants (80.2%) presented with umbilical and PUH, followed by port site hernias (19.8%).

In the present study, 38 patients received general anesthesia and 22 patients had spinal anesthesia, and these findings were in the same line with the study of Hadi *et al.* [14], in which 84 patients had general anesthesia (94%) and two had local anesthesia (4%) and one had spinal anesthesia (2%). However, Vychnevskaia *et al.* [15], mentioned that all included patients in their study received general anesthesia.

Moreover, the study at hand clarified that there was a highly significant statistically difference regarding the operative time, as cases managed using the inlay mesh technique had shorter operative time, with mean of 35.4±0.25 min, than cases managed with the onlay mesh technique, with mean of 50.2±0.14 min. Time saved with the inlay mesh technique results in less anesthetic and operating theater time, hence reducing the risk of general anesthesia and the operating theater cost.

On comparison with other previous studies, Hadi *et al.* [14] recorded that a mean operative time was 30 min (range: 10–68 min). Iversen *et al.* [16] noted that the surgery duration in the patient group with complications had a median of 39 min, range 18–86 min, and without complications had a median of 41 min, range: 16–129 min, and the values did not differ significantly ($P=0.63$). Vychnevskaia *et al.* [15] found that the mean operative time was 33 min (range: 15–100 min).

In the present study, 41 (68.3%) patients had a wall defect less than or equal to 2 cm and 19 (31.6%) patients had a defect less than or equal to 3 cm. A small-sized mesh (4.3 cm) was used in 22 (73.3%) patients and a medium one (6.4 cm) used in eight (26.6%) patients.

Hadi *et al.* [14] found that 43 patients had hernia defects less than two cm and 17 patients had defects less than or equal to three cm. A small-sized mesh was used in 34 patients and medium-sized mesh in 17 patients. Iversen *et al.* [16] performed open procedures for the ventral hernias under the size of four cm in diameter.

Regarding postoperative seroma, group A included one (3.3%) case, whereas group B included seven (23.3%) cases. All of them resolved within three weeks with conservative management. Postoperative wound infection occurred only in one (3.3%) case in group A and six (20%) cases in group B associated with superficial postoperative wound infection. The avoidance of extraperitoneal or prefascial dissection in group A also reduced wound seroma and infection.

The aforementioned findings were further supported with other research studies. Berrevoet *et al.* [13] demonstrated the presence of one asymptomatic seroma, two small hematomas, and no wound complications. Hadi *et al.* [14] recorded one case with seroma and two cases with minor wound infections. The skin stitches were removed to drain the seroma, and the infections were successfully treated with antibiotics. Vychnevskaia *et al.* [15] observed two postoperative hematomas without infection (2%). Skin stitches were separated to drainage the hematomas, and no seroma was noticed.

Regarding postoperative pain in the present investigation, it was noticed that there was a significant statistically difference between both groups, with one (3.3%) case in group A and six (20%) cases in group B, with mean first postoperative day VAS score of 4.4±0.16 vs 5.07 ±1.1, respectively.

Berrevoet *et al.* [13] found that the mean VAS score for postoperative pain at the first postoperative day was 5.4 (range = 0–8.6) and diminished thereafter. Moreover, Hadi *et al.* [14] recorded that nine patients, representing 18%, did not need any analgesics postoperative in the hospital or at home. Thirty-six patients, representing 71%, needed mild to moderate postoperative analgesics such as paracetamol, dihydrocodine, ibuprofen, or co-codamol for 3–5 days. Six patients, representing 12%, needed narcotic analgesics such as morphine sulfate or tramadol postoperatively for maximum three doses in the hospital and subsequently continued with mild or moderate analgesics for a further 3–5 days.

In addition, Vychnevskaia *et al.* [15] mentioned that all the patients had 3 g of paracetamol per day the first 2 days after surgery. After hospitalization, 22 (21.8%) patients did not need any analgesics. Seventy-nine (78.2%) patients needed moderate postoperative analgesics; 2 g of paracetamol per day for 4 days. None required opioids or analgesia.In the present study, there was one (3.3%) case in group A and two (6.7%) cases in group B associated with postoperative recurrence. No significant difference between both groups was observed regarding hernia recurrence at 3, 6, and 12 months.

Berrevoet *et al.* [13] reported that four of 27 recurrences, representing 14.8%, all with extensive shrinkage of the mesh, and all had primary umbilical hernias. The study of Hadi *et al.* [14] recorded one recurrence case at 1 month in their series, in a morbidly obese woman (BMI 47 kg/m^2) who developed a wound infection. The district nurse observed the wound deeply and removed one of the strap-retaining prolene stitches in error. They thought that, this may be led to the displacement of the mesh and hence the recurrence.

Outcomes of both techniques showed that there was a highly statistically significant shorter hospital stay, time of return to work or normal activity, and mean postoperative follow-up in group A when compared with group B. All cases were discharged on the first postoperative day, except one (3.3%) case in group A and six (20%) cases in group B, which were associated with postoperative wound infection and were discharged on the third postoperative day.

Iversen *et al.* [16] reported the median of resuming normal daily activities was 8 days (range: 4.5–20 days) after surgery and the median postoperative duration of the patient's incapacity to work was 8 days (interquartile range: 0–21 days). Moreover, they mentioned that the mean postoperative follow-up was 15.6 months (range: 6–32.3 months).

Conclusions

The inlay ventralex hernia patch is effective and easier technique and can also save the operative time with less postoperative complications (wound seroma, wound infection, postoperative pain. and first postoperative day VAS score) and better outcomes (shorter hospital stay, time of return to work or normal activity, and mean postoperative follow-up) as compared with the classic onlay prolene mesh. So, its use is considered cost-effective.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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