Incisional hernia: conventional open mesh versus laparoscopic repair; a randomized controlled study

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ABSTRACT
Background: Incisional hernia is a common complication after laparotomy. Up to now, there is no consensus on the ideal surgical approach of such hernia. The aim of the present study was to compare the surgical outcomes, feasibility and cost effectiveness of the open mesh repair and laparoscopic repair of incisional hernia.

Methods: A randomized controlled study conducted between August 2015 and September 2019 in which 64 patients with incisional hernias were randomly selected for either open mesh repair (36 patients) or laparoscopic repair (28 patients).

Results: Patients in both groups were similar in their characteristics. The mean operative time was significantly longer in laparoscopic repair than in open mesh repair (128.6±15 minutes versus 89.8±82 minutes, p<0.05). The peri-operative complications and intra-operative blood loss were comparable in the two groups. The use of the drain was significantly higher in open group than in laparoscopic repair group (44.4% versus 10.7%). The overall rate of postoperative complications was similar in both groups, (25% for each group). The rate of wound infection and the length of hospitalization were significantly less in laparoscopic repair group. The results of postoperative pain score, cosmetic outcomes and recurrence rate showed no significant differences between the two groups but patient's satisfaction was significantly higher in laparoscopic repair. p>0.05.

Conclusion: Both laparoscopic and conventional open mesh repair of incisional hernia are equivalent and feasible and safe technique. Laparoscopic repair was superior to open mesh repair in term of surgical site infection, hospital stay and patient’s satisfaction only.

Keywords: Incisional hernias, Open mesh repair, Laparoscopic repair, Surgical outcomes

INTRODUCTION
Incisional hernia which is type of ventral hernia is an abdominal wall hernia that developed at the site of previous surgical incision due to improper wound healing or excessive straining on healing wound due to various factors secondary to breakdown of the facial closure.1

Recurrence of incisional hernia after repair approach 20-45% or even higher despite the significant advancement that have been achieved in the repair of incisional hernia regarding the operative technique and use of synthetic mesh. It is a common surgical condition developed in up to 20%-25% after abdominal surgery and accounts for 20% of all abdominal hernias. Incisional hernia can occur after any abdominal surgery but vertical incisions and lower abdominal incisions are more frequently affected.2

Factors that lead to development of incisional hernia can be classified to firstly: factors related to disease such as urgency of the procedure, site of incision and surgical complications mainly wound or surgical site infection, secondly: factors related to patients including factors that impair wound healing such as obesity, smoking and chronic systemic illnesses like diabetes mellitus (DM), malnutrition, chronic anemia, and chronic use of steroid. Thirdly; factors related to improper surgical techniques such as excessive tension and usage of unsuitable sutures.3
Incisional hernia could be asymptomatic but commonly cause discomfort or pain and cosmetic complaints. They also can result in critical complications such as incarceration, obstruction and strangulation. Incisional hernias usually mandate surgical repair especially when large (larger than 4 cm) or symptomatic to prevent complications, relieve symptoms and better quality of life.5

Open surgical repair using prosthetic mesh have been used to repair the majority of incisional hernias as they decrease the rate of recurrence compared to primary suture repair which have been abandoned by many surgeons. It is worthwhile to know that the recurrence of incisional hernia had been decrease from more than 50-60% after primary suture repair to 10-20 % after the use of prosthetic meshes.5 Although, the open mesh repair is tension free repair, it may result in several complications such as wound and mesh infection which necessitate wound exploration and mesh extraction, mesh shrinkage, seroma and hematoma formation and chronic abdominal wall pain. Furthermore, the recurrence rate after open repair with mesh can reach up to 30%.5

The introduction of laparoscopic repair for management of ventral hernias including incisional hernia have gained wide acceptance and increasing interest in to lessen the complications and recurrence rates of open mesh repair besides the general advantages of laparoscopic surgery such as small wounds, less intraoperative blood loss and infectious complications, better visualization of facial defect without aggressive dissection of previous scar and abdominal wall layers, less post-operative pain, shorter hospital stay and decrease the rate of recurrence.5,6 Several previous studies have been published comparing the feasibility and surgical outcomes of both open mesh repair and laparoscopic repair of primary and recurrent incisional hernias. Some of these studies demonstrating that there was no favorable method of repair over other, others showed the advantages of laparoscopic over open mesh repair and some other studies showed that both studies are suitable and each one has its own and specific indications. Therefore, no technique is the best method and controversy and debate is still ongoing regarding the best solution.

The main purpose of the present study was to compare the feasibility, complications and short and long-term surgical outcomes of open mesh repair and laparoscopic repair among our patients who presented with primary and recurrent mid-line incisional hernias.

**METHODS**

This is a prospective randomized controlled study included 64 patients presented with incisional hernias (both primary and recurrent) of midline (vertical) type who presented for hernia repair of either open mesh repair or laparoscopic repair for the period from August 2015 and September 2019 in major Basrah private hospital in Basrah province, Iraq. All patients were fully evaluated preoperatively by obtaining a detailed history and thorough physical examination. Routine blood and imaging investigations and informed written consents were also obtained from all patients. Exclusion criteria include patients with non-midline hernias such as hernias after cesarean section and incisional hernias post appendectomy.

The participant patients in this study were randomly presented for either open conventional mesh repair or laparoscopic repair. Patients with limited financial state and those with chronic obstructive pulmonary disorder (COPD) in whom laparoscopy is contraindicated were offered for open mesh repair and represented in group A (36 patients), while those patients offered for laparoscopic repair were included in group B (28 patients).

**Procedures**

**Open conventional mesh repair (group A)**

Operations were done mainly under general anesthesia or spinal anesthesia on few occasions. Excision of previous scars was a routine, followed by careful and delicate dissections of hernia sac. Opening of the sac and separation and release of the contents then done with excision of the entrapped and unhealthy omentum and return of the bowel and healthy omentum to abdominal cavity. The facial defect then cleared all around. The mesh used was polypropylene mesh and the repairs were on lay repair in which the mesh was fixed to anterior rectus sheath, Suction drains in this approach were optional according to surgeon preference and operation circumstances.

**Laparoscopic repair (group B)**

All operations in this group were conducted under general anesthesia with endotracheal intubation. Monitors and screen are placed on the patients affected side. The surgeon and the assistant (cameraman) stand on the opposite side. The trocars are inserted along the anterior axillary lines on both sides. The first 10 mm or 12 mm trocar which is used as a port of laproscope and entry of mesh is typically placed superior and 5 cm from original incision (scar) for sake of safety. Then, two 5 mm trocars are placed under laparoscopic guidance with the distance between the trocars was 10-15 cm to avoid instruments interference. The operation starts with sharp separation of adhesion using a focus harmonic scissors from the fascia and muscles surrounding the hernia ring to be exposed for 5 cm all around. The site and the size of abdominal wall defect are allocated and marked by sterile 21-gauge syringe needles inserted through the abdominal wall after the pneumoperitoneum pressure is reduced. The size of the mesh which of a composite type is then determined which should cover the defect with 5 cm extension in all directions. Two non-absorbable nylon sutures were tie on either side of upper end of the mesh with another two polypropylene sutures on opposite lower end for ease of...
identification. Mesh then anchored using spinal needles. Tackers were also used for mesh fixation. Tight compressive dressing was put over the whole defect at the end of the procedure. Gastric and bladder decompression in this group were also optional.

Postoperative management of all patients in both groups was similar. All patients received pain killers in form of injectable diclofenac or tramadol shifted thereafter on oral analgesic according to patient's condition and demand. All patients were ambulated an encouraged oral feeding 6-12 hours postoperatively with exception in patients with persistent ileus in whom nasogastric tube was placed to be removed after resolution. Patients were discharged after wound was inspected for any infection, seroma or hematoma formation and after removal of drains and when they are fully ambulated. Patients were asked to be seen 1 week, 1 month, and every 3 months later for one-year duration after surgery for follow up and evaluation of surgical outcomes and complications of two approaches of incisional hernia repair.

The intra-operative and postoperative surgical outcomes of open mesh repair and laparoscopic repair of incisional hernias in respect of perioperative complications, duration of surgery, postoperative pain and complications, hospital stay, return to work, recurrence, aesthetic aspect, patients satisfaction and financial cost were compared and analyzed. The results were collected and analyzed using the statistical package for social science (SPSS) version 21 (SPSS Inc., Chicago, Illinois, USA). The results of both groups in this study were compared using the Chi-squared and t-test. p value less than 0.05 was considered to be statically significant.

The patients were investigated and treated according to the protocols.

**RESULTS**

This is a prospective study conducted between August 2015 and September 2109 included 64 patients presented with primary and recurrent midline incisional hernias (38 males and 26 females) with ages ranges from 26 to 67 years, means 46.7±3 year who were randomly chosen to undergo either open mesh repair represented by group A (n=36) or laparoscopic repair (n=28). Patients in both groups were similar in their characteristics such as age sex ratio, body weight, size of hernia, co-morbidities, and anaesthetics risk. (Table 1)

| Patients characteristics | Group A (open repair) (n=36) | Group B (Laparoscopic repair) (n=28) |
|--------------------------|-----------------------------|-------------------------------------|
| Age (mean)               | 53.6±7                      | 55.3±2                              |
| Male: female             | 15:21                       | 16:12                               |
| Body weight kg (mean)    | 88.1 ± 25                   | 91.1 ± 6                            |
| Incisional hernia        |                             |                                     |
| Primary                  | 30                          | 21                                  |
| Recurrent                | 6                           | 7                                   |
| Size of hernia defect cm (average) | 6 (2 - 8) | 5 (4 – 7)                           |
| Co-morbidities           | 7                           | 6                                   |
| Anaesthetic risk (ASA category) |             |                                     |
| I                        | 11                          | 10                                  |
| II                       | 20                          | 15                                  |
| III                      | 4                           | 2                                   |
| IV                       | 1                           | 1                                   |

Table 2: Peri-operative and intra-operative outcomes and complications.

| Outcomes and complications | Group A (open repair) (n=36) | Group B (laparoscopic repair) (n=28) | P value   |
|----------------------------|-----------------------------|-------------------------------------|-----------|
| Incarcerated hernia        | 8                           | 6                                   | p< 0.05   |
| Operative time (min.) Mean | 89.8±82                     | 128.6±15                            | p> 0.01   |
| Blood loss (ml)            | 50 ml                       | 45 ml                               | p> 0.05   |
| Intra-operative complications |                             |                                     | p> 0.05   |
| Serosal bowel injury       | 2                           | 3                                   |           |
| Enterotomy                 | 1                           | 0                                   |           |
| Bladder injury             | 0                           | 1                                   |           |
| Bleeding                   | 3                           | 4                                   |           |
| Others                     | 2                           | 2                                   |           |
| Drain                      | 16 (44.4%)                  | 3 (10.7%)                           | p<0.05    |
| Conversion rate            | -                           | 3                                   |           |
Table 3: Postoperative complications.

| Postoperative complications | Group A (Open Repair) | GroupB (Laparoscopic repair) | P value |
|-----------------------------|-----------------------|-----------------------------|---------|
|                             | N (%)                 | N (%)                       |         |
| Wound infection             | 4 (11.1)              | 2 (7.1)                     | <0.001  |
| Haematoma formation         | 3 (8.3)               | 2 (7.1)                     | >0.01   |
| Seroma                      | 5 (13.8)              | 3 (10.7)                    | >0.05   |
| Wound dehiscence            | 2 (5.5)               | 0                           |         |
| Sever postoperative pain (VAS) |                 |                             | >0.01   |
| Mild (1-3 score)            | 12 (33.3)             | 8 (28.6)                    |         |
| Moderate (4-7 score)        | 18 (50)               | 16 (57.1)                   |         |
| Severe (>7 score)           | 6 (16.7)              | 4 (14.3)                    |         |
| Ileus                       | 3 (8.3)               | 2 (7.1)                     | >0.01   |
| Postoperative bleeding      | 1 (2.7)               | 0                           | >0.01   |
| Respiratory tract infection | 1 (2.7)               | 2 (7.1)                     | >0.05   |
| Readmission                 | 3 (8.3)               | 1 (3.6)                     | >0.01   |
| Re-exploration              | 1 (2.7)               | 0                           | >0.01   |
| Length of hospital stay (day) | 4 (2-6)              | 2.5 (2-4)                   | <0.001  |
| Aesthetic issues            |                       |                             | >0.01   |
| Unsatisfied                 | 5 (13.8)              | 4 (14.3)                    |         |
| Satisfied                   | 19 (52.8)             | 12 (42.9)                   |         |
| Excellent                   | 12 (33.3)             | 12 (42.9)                   |         |
| Overall complications       | 9 (25)                | 7 (25)                      |         |
| Cost                        | Less cost             | More cost (2-5 folds)       | <0.05   |
| Mortality                   | 0                     | 0                           |         |
| Follow up period (months)   | 12 (6-18)             | 12 (6-12)                   |         |
| Recurrence                  | 4 (11.1)              | 2 (7.1)                     | >0.01   |

The size of defect and the contents of the hernias were comparable in both groups. The contents were omentum in the majority of hernias (87%) followed by mixed omentum and small bowel 8% and 5% of the hernias contain small bowel only. Incarcerated hernias were observed in 8 patients in open mesh repair and in 6 patients in laparoscopic repair group.

The mean duration of surgery was significantly longer in laparoscopic repair than in open mesh repair (128.6±15 minutes versus 89.8±82 minutes, p<0.05). The intra-operative blood loss was comparable in the two groups. Regarding the intra-operative accidents, two patients in open group and 3 patients in laparoscopic group had serosal bowel injury. Enterotomy without spillage of intestinal content was recorded in open repair due to dense adhesions of the bowel with omentum for which primary suturing was done. One patient in laparoscopic group had small size bladder injury that had been closed by endo-loop suturing and Foley's catheters were inserted postoperatively. The intra-operative bleeding was comparable in both groups. It was mild to moderate bleeding and it was easily and rapidly controlled. Three cases in laparoscopic group were converted into open mesh repair due to difficult adhesiolysis and large defect. Although the use of the drains was optional in both groups, the use of the drain was significantly higher in open group than in laparoscopic repair group (44.4% versus 10.7%). The above findings are demonstrated in Table 2.

The overall rate of postoperative complications was similar in both groups, (25% for each group). Wound infection was significantly higher in open mesh repair, (11.1% versus 7.1 %.) Although the postoperative pain and analgesic or narcotics use was less in laparoscopic repair group, but the difference didn’t reach the significant level (p>0.01). Ileus was observed in one patient in open mesh group and two patients in laparoscopic group mainly in those with recurrent hernias that associated with extensive manipulation and adhesiolysis. All these patients were managed successfully. By conservative measures.

Readmission was recorded in patients in open group and one patient in laparoscopic group, one patient only in open mesh group needed re-exploration due to postoperative bleeding for proper and control hemostasis.

The results showed that the hospital stay was significantly shorter in laparoscopic repair group than in open mesh repair (2.5 days versus 4 days, p<0.05).

Regarding the cosmetic results, the findings showed that there were no significant differences between tow techniques. The cost of laparoscopic repair, however, were
Incisional hernia is a relatively common surgical complication developed in up to 15-20% following laparotomy. It can occur after any abdominal surgery both iatrogenic and traumatic.\textsuperscript{5,6} Although small asymptomatic incisional hernia can be treated conservatively with low risk of complications, large and symptomatic hernia usually requires surgical repair to relieve the symptoms, prevent complications, better quality of life and for better aesthetic issues especially among females patients.\textsuperscript{5,6}

Open suture repair which was practiced previously for incisional hernia repair, nowadays have been abandoned and not recommended due to bad reputation of high recurrence rate which is 2-5 times greater than mesh repair, hence suture repair should be considered obsolete.\textsuperscript{6} Although the introduction of mesh for incisional hernia repair had improved the surgical outcomes, the recurrence rate had still a major concern which remains as high as 20-30\% particularly for big and recurrent hernias due to extensive tissue dissection and repair under tension besides the use of drains which increase the rate of infection which is a major risk factor for development of incisional hernia. In the modern surgical era, the laparoscopic hernia repair should have all the advantages of laparoscopic surgery in particularly avoiding large wounds, decreasing blood loss and wound infection with less postoperative pain and analgesic use as well as short hospital stay and early return to work.\textsuperscript{7}

Since the first laparoscopic incisional hernia repair by Blanc and Booth in 1993 7 several advancements and modifications had been occurred on laparoscopic repair of incisional hernias.\textsuperscript{7} Several studies had been conducted comparing the results and efficacy of open mesh repair and laparoscopic repair of ventral hernias including incisional hernia.\textsuperscript{5-10}

There was no general agreement that in favor one technique on the other. Some studies showed the advantages of laparoscopic repair including very small wounds, avoidance of extensive dissection and hence less postoperative pain and need for analgesic, low wound infections and short hospital stay.\textsuperscript{11-13} While other studies concluded that the outcomes of both approaches were comparable.\textsuperscript{14-17} We conducted this study to present our findings regarding the surgical outcomes, advantages and limitations of both techniques among our patients who presented with primary and recurrent midline incisional hernia and compare our results with similar researches.

In present study, a total of 64 patients were randomly presented for either conventional open mesh repair (36 patients) or laparoscopic repair (28 patients). Patient's characteristics including mean age, males to female's ratio, body weight, co morbidities and the size of the defect were comparable as shown in table 1. The size of the fascial (hernia) defect was not a prerequisite or substantial for the choice of the repair. In our study, regarding the peri-operative complications, we found that the operative time which is crucial factor in assessing the effectiveness and feasibility of the procedure was significantly longer for laparoscopic repair. This could be justified by steep learning curve. Our findings were consistent with that of Ekher et al.\textsuperscript{16} Studies by Thota et al and Pring et al showed that the mean operative time was similar comparable in both groups whereas study by Omli et al showed significant reduced operative time in laparoscopic repair.\textsuperscript{15,18,19} The peri-operative complications and the average blood loss were comparable in both groups. The use of the drains, however, was higher in open mesh repair. Serosal bowel injury was recorded in 2 patients in open mesh repair and in 3 patients in laparoscopic repair. One patient in open group developed inadvertent enterotomy which was sutured transversely whereas bladder injury was recorded in one patient in laparoscopic repair group. Soliani et al recorded in their similar research that peri-operative morbidity and mortality were similar in both open and laparoscopic repair but the operative time and hospital stay were shorter in laparoscopic repair.\textsuperscript{17} They concluded that laparoscopic repair could be considered safely to all patients with incisional hernias regardless of their characteristics. Sains et al in their randomized clinical trial of laparoscopic versus incisional hernia repair found that the intra-operative average blood loss and the number of the patients receiving a wound drain was significantly less in the laparoscopic group.\textsuperscript{20} They also reported that peri-operative complications and operative time were significantly higher after laparoscopy. Zhang et al in their systemic review and meta-analysis of 11 randomized controlled series that compared the surgical outcomes of laparoscopic incisional and ventral hernia repair with open mesh repair concluded that laparoscopic incisional hernia repair is effective and valid alternative to the open repair.\textsuperscript{15} It is associated with less wound infection but carries increased risk of bowel injuries compared with open mesh technique.

The postoperative complications and the surgical outcomes in this study showed that, laparoscopic repair associated with low incidence of surgical site infection, shorter hospital stay, significant decrease in hernia recurrence after follow-up period of 12 months and better patients’ satisfaction. The most frequent complications encountered after incisional hernias repair in most studies including ours were seroma formation and wound related complications. All similar studies reported less wound infection except the randomized controlled trial by Asencio et al.\textsuperscript{8,9,10,11,15,21} The post-operative pain assessed immediately after surgery, 24 hours, 3rd postoperatively and one week later by visual analogue scale and use of analgesics were comparable in both groups and no significant difference was noted in our study. Similar
results were recorded by Pring et al and Sauerland et al. Thota et al showed significant decrease in postoperative pain after laparoscopic repair. Mishra et al and Lavanchy et al reported that although laparoscopic repair of incisional hernia and ventral hernia was significantly superior to open mesh repair in terms of less intraoperative blood loss, fewer surgical site infection, reduced hospital stay and better cosmetic outcomes, there were no significant differences in the postoperative pain scores and recurrence of hernias between the two groups. Their results are consistent with ours.

Postoperative ileus was recorded in 3 cases in open mesh repair and 2 cases in laparoscopic repair. The difference was not significant, and all these patients were treated successfully by conservative measures. Similar findings were observed by Sains et al. Heinford et al and Rogmark et al in their large series of 850 consecutive patients who presented for laparoscopic repair for their incisional hernias reported that prolonged postoperative ileus was recorded in 3% of the patient.

Our results showed that the hospital stay and faster return to work were significantly less in laparoscopic repair than with open mesh repair. Similar studies found that laparoscopic repair is superior to open mesh repair regarding the hospital stay and recurrence rate. Other studies on the other hand, showed that laparoscopic incisional hernia repair does not seem to be better procedure than the open technique in terms of operative time, hospitalization, overall complications, postoperative pain or quality of life.

Sauerland et al and Forbes et al found that short-term results indicate that laparoscopic incisional hernia repair is associated with a shorter operative time and hospitalization and thus faster return to work. They reported that the laparoscopic technique is safe in spite of the risk of adhesiolysis, but long-term follow-up is required to know whether laparoscopic repair of incisional hernia is feasible and effective procedure.

The recurrence rate after a mean follow up period of 12 months in laparoscopic group was 7.1% (2 patients) and 11.1% (4 patients) in the open group. The difference however was not significant. Wound infection, obesity, large defect and recurrent incisional hernias were independent risk factors. Lavanchy et al showed in their study similar findings that there was no significant difference in recurrence rate between laparoscopic and open group after follow-up period of 5.5 years. Recurrence was associated with large defect, obesity, previous repair, and surgical site infection. Similar findings were also recorded by other researchers, whereas Froylich et al and Jagan et al recorded that risk of recurrence of incisional repair is less after laparoscopic repair particularly in obese patients compared with open mesh repair after a long-term follow up.

Ramshaw et al and Heinford et al and in their large series recorded a recurrence rate of 4.7% after laparoscopic repair. Forbes et al reported in their meta-analysis of 8 studies which compared the laparoscopic and open mesh incisional or ventral hernia repair that there was no difference between the two groups in hernia recurrence rate. They also reported that the laparoscopic repair has superior outcomes to open repair due to shorter hospital stay, fewer wound and hemorrhagic complications.

The cosmetic outcomes of both procedures were comparable in our study, since laparoscopic repair keeps the previous scar and the sac is retained and in open mesh repair there was a new wound after excision and removal of old scar, therefore there was no significant difference. Patient’s satisfaction however was higher after laparoscopic repair due to rapid recovery and faster return to work. Little is written in previous similar studies about satisfaction feeling and cosmetic consequences in patients who undergo either open mesh or laparoscopic incisional hernia repair. Evangelos et al and Jagan et al showed that the cosmetic end result was better in laparoscopic repair patients.

Our findings showed that the laparoscopic repair more costly than open mesh repair (2-5 folds). Fernandez et al showed that the cost of disposable surgical supplies was higher with laparoscopic repair, but since this approach is associated with a reduced postoperative complications and hospitalization, so the overall total costs were lower than open mesh repair and the procedure was considered as a cost-effective. The INCH trial by Poelman et al reported that laparoscopic repair resulted in rapid recovery and early return to work and hence is a more cost-effective. Lastly, Kingsnorth et al recommended that large (more than 10 cm) and complex incisional hernia especially those with loss of domain are better to repair by open mesh technique. Smaller incisional hernias with diameter less than 10 cm can be repaired successfully by a laparoscopic approach, therefore is no consensus on superiority of one of these procedures over the other.

CONCLUSION

Both laparoscopic and conventional open mesh repair of incisional hernia are equivalent and feasible and safe technique. The surgical outcomes of both techniques are comparable in terms of peri-operative and postoperative complications, postoperative pain and need for analgesics, cosmetic results and recurrence rate regardless of patient age, sex, body weight and co-morbidities. Laparoscopic repair was superior to open mesh repair in term of surgical site infection, hospital stay and patient’s satisfaction only. Moreover, the operative time was longer for laparoscopic hernia repair and it was more costly. For large incisional hernias with a defect more than 10 cm with loss of domain, open mesh approach is preferable to decrease the recurrence rate.

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