

## Meta-analysis of randomized controlled trials comparing laparoscopic with open mesh repair of recurrent inguinal hernia

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### ABSTRACT

**Background:** The repair of recurrent inguinal hernia is a more complex undertaking, accounting for up to 15 per cent of all hernia surgeries whether by open tension free or laparoscopic surgery. Advantages of laparoscopic procedures may include a reduction in postoperative pain and hospital stay, and the ability to undertake a simultaneous repair of symptomatic incipient contralateral herniation. However, open repair can be performed under local anesthesia and is preferred by many surgeons. However, there is still much controversy about the ideal technique for recurrent hernia repair. **Objective:** To compare between the two approaches Open tension free and laparoscopic repair of recurrent inguinal hernia after a previous mesh repair, in terms of operative time, infection, postoperative pain scores, recurrence and chronic pain. **Methods:** This study is metanalysis of prospective randomized controlled studies that was published at the period between 2008 and 2018, between open tension free and Laparoscopic (mainly TAPP) repair of recurrent inguinal hernia after a previous mesh repair. For this systematic review, PubMed/Medline and ScienceDirect online databases were searched using the keywords operative time, infection, postoperative pain scores, recurrence and chronic pain. Abstracts of articles identified were reviewed, and then relevant articles were retrieved in full. Papers were only included if data on at least one of the main outcome measures was obtainable. **Results:** The results of the current meta-analysis showed that significantly fewer patients with Post-operative pain scores were found in the laparoscopic group. The main disadvantage of laparoscopic repair has been the duration of the operation as the mean operative time was longer in the laparoscopic operations, but without significant statistical difference. The Metanalysis of re-recurrence rate was lower in the laparoscopic than in the open group, with statistically significant difference, while the meta-analysis of chronic pain showed non-significant difference between the two approaches. Wound infection was discussed in two studies, with no statistically significant difference. **Conclusion:** The main advantage of the laparoscopic approach is decreasing the risk of recurrence and post-operative pain scores. No significant difference of outcome regarding chronic pain, surgical site infection or operative time.

**Keywords:** recurrent inguinal hernia, open tension free, laparoscopic, recurrence, chronic pain, operative time, infection, postoperative pain.

### INTRODUCTION

Hernia repair is one of the commonest procedures performed by general surgeons; indeed, it has been stated that 'the history of hernia repair is the history of surgery. The most common technique for inguinal hernia repair was originally an open, tissue-based suture repair, which eventually evolved to commonly use prosthetics (with various fixation devices of sutures, staples, tacks, and glue) for a tension-free repair with a significantly lower recurrence rate<sup>(1)</sup> and lower chronic pain after surgery<sup>(2)</sup>.

Laparoscopic repair of the inguinal hernia is becoming an increasingly popular method of

herniorrhaphy. The advent of laparoscopy has revolutionized abdominal surgery and a large body of evidence has been amassed to compare laparoscopic and open techniques in the repair of primary inguinal hernias<sup>(3)</sup>. Advantages of laparoscopic procedures may include a reduction in postoperative pain and hospital stay, and the ability to undertake a simultaneous repair of symptomatic incipient contralateral herniation. However, open repair can be performed under local anesthesia and is preferred by many surgeons.<sup>(4)</sup>

The repair of recurrent inguinal hernia is a more complex undertaking, accounting for up to 15 per cent of all hernia surgeries<sup>(5)</sup>. Since the use

of prosthetic mesh for the surgical repair of inguinal hernias has become increasingly popular, mesh material introduced during a previous operation is being detected in a growing number of patients undergoing surgery for recurrent hernia. This applies to at least 10% of recurrences.<sup>(6)</sup>

Recurrent hernias greatly increase the complexity of subsequent repair. If left untreated, severe complications can result such as incarcerated hernia, digestive obstruction, or strangulated hernia. Highly complex abdominal surgery is often required to repair recurrent hernias. Success rates are generally lower for each re-operation.

In this context, the purpose of this study is to compare outcome of laparoscopic surgery with that of open tension free mesh repair for recurrent inguinal hernia.

## AIM OF THE WORK

The purpose of this study is to compare outcome of laparoscopic surgery with that of open tension free mesh repair for recurrent inguinal hernia regarding recurrence, chronic pain, operative time, infection and postoperative pain scores.

## METHODS

### *Search Strategies:*

A systematic review of literature was conducted to locate relevant studies on different surgical techniques used in recurrent inguinal hernia repair. Both of ScinceDirect and Pubmed/Medline electronic databases were searched for the published literature in the period from Jan 2008 to December 2018 using the following keywords: "recurrent inguinal hernia," "recurrence," "postoperative pain scores," "operative time," "chronic pain," "infection," and "operative time." Abstracts of the retrieved papers were screened by two independent authors, and articles that met the inclusion and exclusion criteria were fully reviewed. Studies were included only if the complications were clearly identified and described in the paper. All the eligible articles were assessed independently for inclusion in the meta-analysis. The entire process was conducted according to the PRISMA guidelines

### **Inclusion criteria:**

This study included comparative and cohort studies that reported on outcome and complications for recurrent inguinal hernia repair after a previous mesh repair managed with open tension free or laparoscopic techniques mainly Trans-abdominal pre-peritoneal (TAPP) technique. Filters were set for articles in English and only studies on adult patients were reviewed.

### **Exclusion criteria:**

Studies that were entirely literature reviews, technical descriptions or case report studies. Also, other studies that included patients with age less than 18 years of age, contraindication to general anesthesia (for Endoscopic repair) / Regional anesthesia (for open repair), patients with complicated inguinal hernia like obstruction, strangulation or gangrene. Patients who have undergone previous lower abdominal surgeries patients with Co morbidities that affect the healing process such as chronic diseases including liver cell failure, renal failure and heart failure, Oncology patients treated with radiotherapy or chemotherapy and patients with immunosuppression.

### **Outcome assessment:**

1. **Primary outcome measures:** Recurrence, Chronic pain
2. **Secondary outcome measures:** Postoperative pain scores, Superficial wound infection, Operating time.

**Data extraction:** The data extracted from the included articles included: study ID, study design, sample size, quality assessment, surgical technique, follow-up period, effect estimates of the study outcomes.

**Quality Assessment:** The retrieved RCTs were assessed for evidence of publication bias according to the Cochrane handbook Risk of bias assessment tool. The authors' judgments were categorized as 'Low risk,' 'High risk' or 'Unclear risk' of bias (7) For the observational studies, the Newcastle-Ottawa Scale 'NOS' was applied for quality assessment, with application of a star rating scale for each study<sup>(8)(9)</sup>.

### **Statistical analysis:**

Meta-analysis was performed using comprehensive metanalysis version 3.0 software. In case of qualitative outcomes Mean  $\pm$  SD and total sample count were collected then the mean differences were pooled to calculate the weighted mean, while in case of quantitative outcomes

events and total sample count were collected then the relative rates were pooled to calculate the weighted relative rate. Heterogeneity index was calculated to test variation of pooled estimated for each outcome. Forest plot were used to present the individual and weighted estimates. The level of significance was taken at P value < 0.050 is significant, otherwise is non-significant.

#### Ethical Considerations:

The study protocol was approved by the ethical committee of Ain-Shams University. This systematic review did not need direct contact with

the individual patients, and only included some previously published data for a further analysis.

## RESULTS

The initial search provided 340 studies. After duplicates removal and abstract screening, 82 articles were retrieved for full-text assessment, of which 5 studies fulfilled the eligibility criteria and were included in the final analysis. Figure (1) shows a flow diagram of the literature search and study selection.

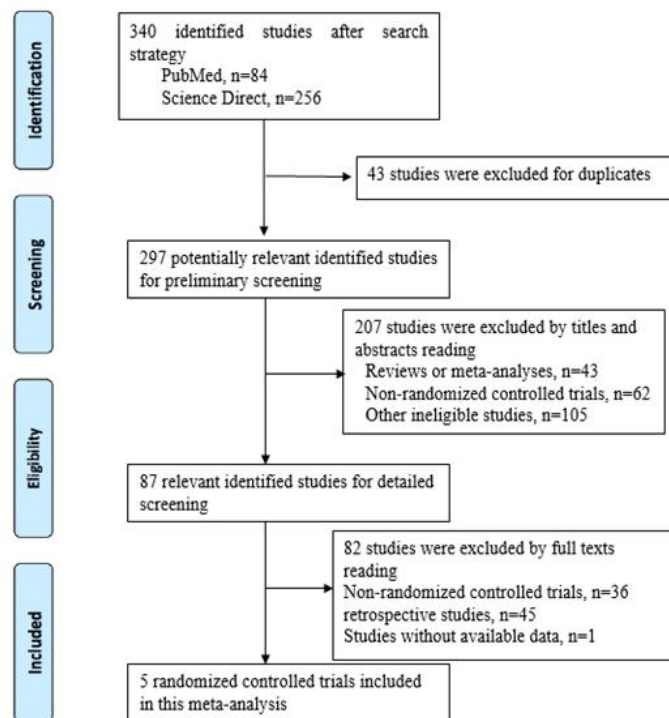


Figure (1): PRISMA Flow chart describing the literature search

#### Risk of bias among included studies:

The quality of the included studies was relatively moderate. Among the observational studies, 14 studies were of fair quality in methodology, while three studies were of good quality. Only three studies were of poor quality. Whilst among the randomized studies (RCTs), all of the included studies had a low risk of bias regarding random sequence generation, blinding of participants and personnel, and blinding of outcome assessment. Three out of the five studies

had low risk regarding the allocation concealment, incomplete outcome data, and selective reporting. All of the included studies had unclear risk of bias regarding other biases.

#### Study characteristics:

The included studies gave details on at least one of the outcome measures in 1638 patients. All patients were within adult population and were operated for repair of recurrent inguinal hernia. Study sizes ranged from 52 to 1224 cases.

**Table (1):** A summary of the studies included in this meta-analysis also showing Patients' demographic characteristics

Study	Country	Year	Study design	Duration of follow up	Number		
					Total	Open	Laparoscopic
<i>Thue Bisgaard et al.</i>	Denmark	2008	Prospective	8 years	1224	1124	100
<i>Z. Deme Trashvili et al.</i>	Georgia	2011	prospective	3 to 7.5 years	52	28	24
<i>M. Bignell et al.</i>	United Kingdom	2012	prospective	10 years	120	60	60
<i>Aly Saber et al.</i>	Egypt	2015	prospective	28-73 months	120	60	60
<i>B Yang et al.</i>	USA	2018	prospective	46.2 +/- 8.5 months	122	63	59

**I- Primary Outcome:****I- Recurrence:**

Table (2) and figure (1,2) show that: Recurrence was reported in the five included studies. One study did not report recurrence in both groups (excluded), one study showed significant lower risk in laparoscope group and

three studies showed non-significant lower risk in laparoscope group. There was non-significant heterogeneity among these studies. Thus, we performed the statistics using a fixed-effects model, and the results showed that recurrence was significantly lower risk among laparoscope than in open.

**Table (2):** Metanalysis for recurrence

Study	Laparoscope		Open		RR (95% CI)	z-value	P-value	Weight
	Total	%	Total	%				
<b>Bisgaard et al., 2008</b>	590	1.9%	749	10.4%	0.20 (0.11–0.37)	5.220	<0.001*	67.5%
<b>Trashvili et al., 2011</b>	24	0.0%	28	0.0%	--	--	--	
<b>Bignell et al., 2012</b>	60	7.0%	60	8.0%	0.88 (0.25–3.08)	0.208	0.835	15.5%
<b>Saber et al., 2015</b>	60	5.0%	60	6.3%	0.80 (0.18–3.50)	0.296	0.767	11.3%
<b>Yang et al., 2018</b>	59	1.7%	63	4.8%	0.40 (0.05–3.22)	0.861	0.389	5.7%
<b>Overall effect</b>					0.31 (0.19–0.50)	4.675	<0.001*	100%
<b>Heterogeneity</b>	<b>I<sup>2</sup></b>		52.136		<b>P-value</b>	0.099		

RR: Relative rate, CI: confidence interval, \*Significant

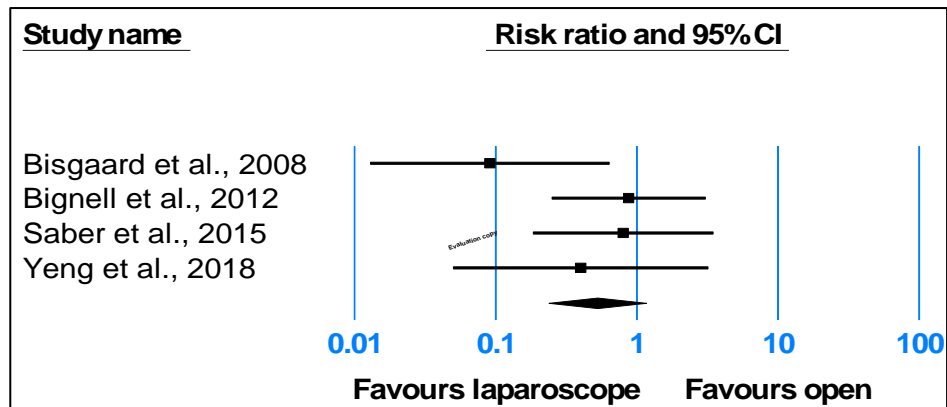


Figure (1): Forest plot for recurrence

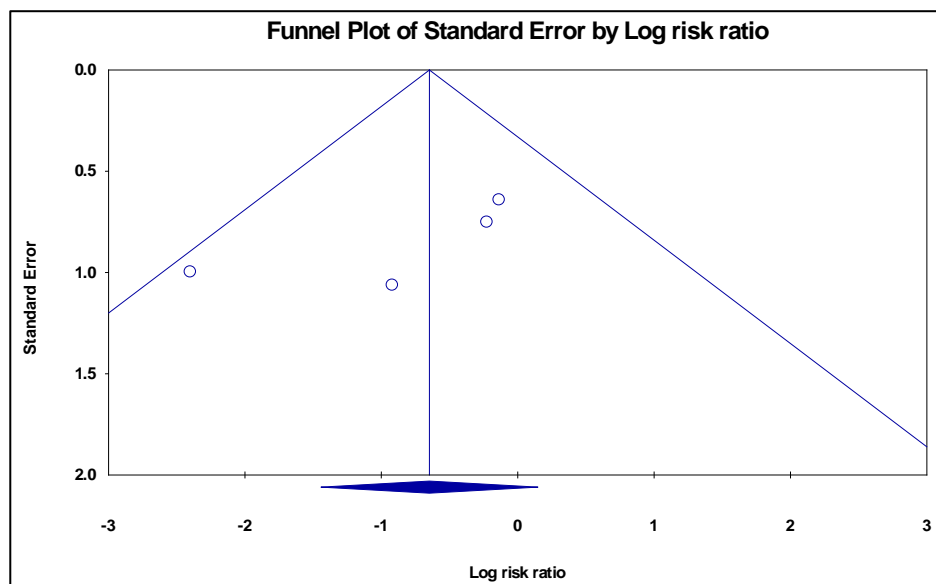


Figure (2): Funnel plot for recurrence

## 2- Chronic Pain:

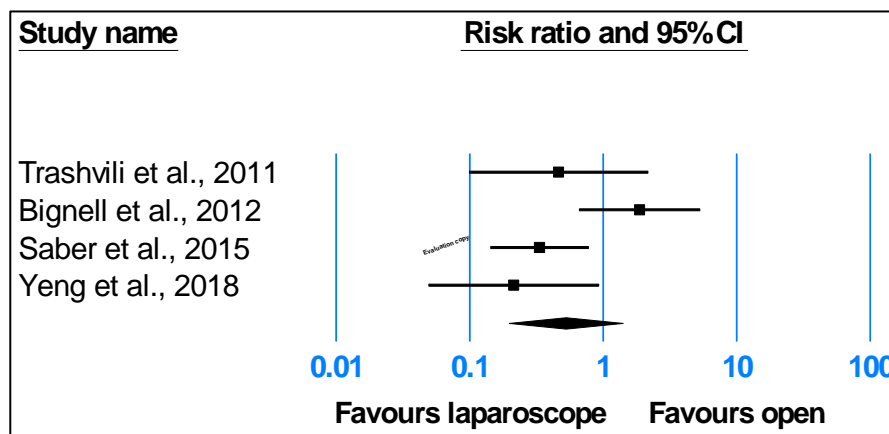
Table (3) and figure (3,4) show that: **Chronic pain** was reported in the four included studies. One study showed non-significant higher risk in laparoscope group, one study showed non-significant lower risk in laparoscope group and two studies showed significant lower risk in

laparoscope group. There was significant heterogeneity among these studies. Thus, we performed the statistics using a random-effects model, and the results showed that chronic pain were not significantly lower risk among laparoscope than in open.

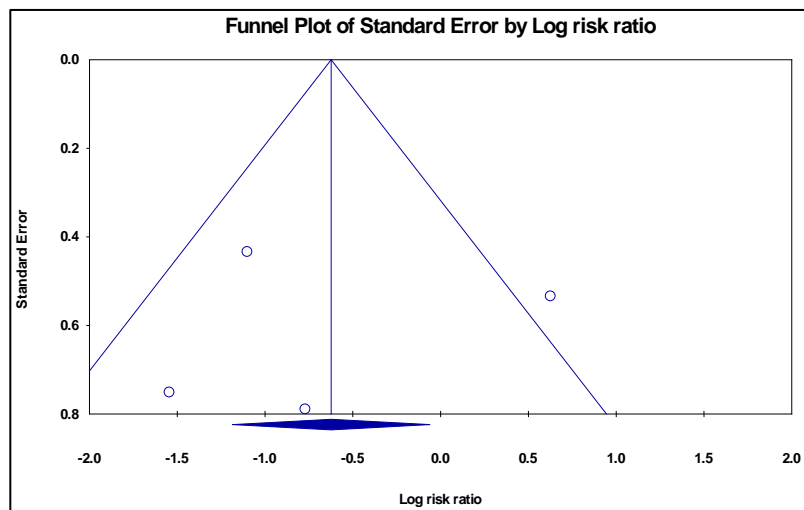
**Table (3): Metanalysis for chronic pain**

Study	Laparoscope		Open		RR (95% CI)	z- value	P- value	Weight
	Total	%	Total	%				
Trashvili et al., 2011	24	8.3%	28	17.9%	0.46 (0.10–2.18)	0.973	0.331	20.2%
Bignell et al., 2012	60	15.0%	60	8.0%	1.88 (0.66–5.35)	1.175	0.240	27.7%
Saber et al., 2015	60	10.0%	60	30.0%	0.33 (0.14–0.78)	2.528	<b>0.011*</b>	31.0%
Yang et al., 2018	59	3.4%	63	15.9%	0.21 (0.05–0.93)	2.051	<b>0.040*</b>	21.2%
<b>Overall effect</b>					0.52 (0.20–1.40)	1.293	0.196	100%
<b>Heterogeneity</b>	<b>I<sup>2</sup></b>		63.423		<b>P-value</b>	<b>0.042*</b>		

RR: Relative rate, CI: onfidene interval, \*Significant



**Figure (3): Forest plot for chronic pain**



**Figure (4): Funnel plot for chronic pain**

**II- Secondary Outcome:****1- Post-Operative Pain Scores:**

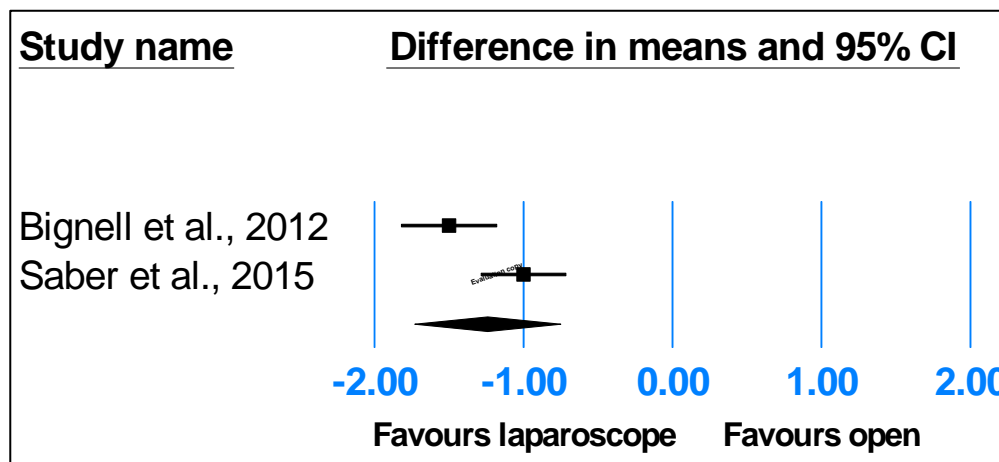
Table (4) and figures (5) show that: Pain score was reported in the two included studies. The two studies showed significant lower pain in laparoscope group. There was significant

heterogeneity among these studies. Thus, we performed the statistics using a random-effects model, and the results showed that pain score was significantly lower in laparoscope group than in open group.

**Table (4): Metanalysis for Post-operative pain score**

Study	Laparoscope		Open		Difference Mean±SE (95% CI)	z-value	P-value	Weight
	N	Mean±SD	N	Mean±SD				
Bignell et al., 2012	60	2.0±0.8	60	2.0±1.0	-1.5±0.2 (-1.8–1.2)	9.073	<0.001*	48.9%
Saber et al., 2015	60	2.0±0.7	60	2.0±0.9	-1.0±0.1 (-1.3–0.7)	6.794	<0.001*	51.1%
<b>Overall effect</b>					-1.2±0.2 (-1.7–0.8)	4.979	<0.001*	100.0%
<b>Heterogeneity</b>	<b>I<sup>2</sup></b>		80.400		<b>P-value</b>	<b>0.024*</b>		

CI: onfidene interval, \*Significant

**Figure (5): Forest plot for pain score**

*Funnel plot for pain score among could not be performed as the included studied were less than three.*

**2- Infection:**

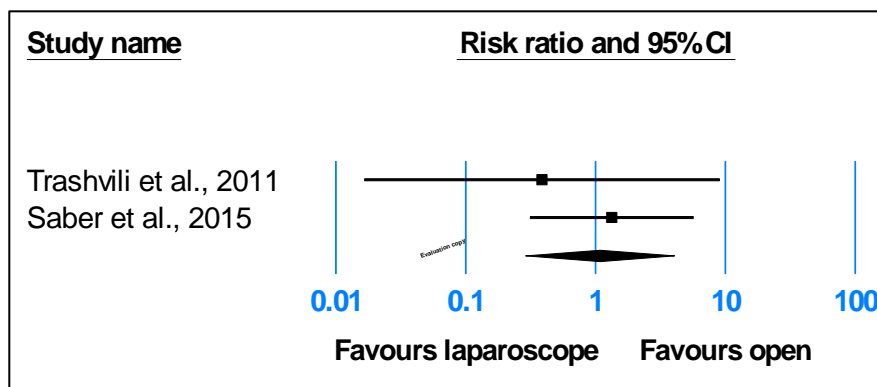
Table (5) and figure (6) show that: Infection was reported in the two included studies. One study showed non-significant higher risk in laparoscope group and one study showed non-significant lower risk in laparoscope group. There

was non-significant heterogeneity among these studies. Thus, we performed the statistics using a fixed-effects model, and the results showed that Infection were not significantly different among laparoscope and open.

**Table (5): Metanalysis for infection**

Study	Laparoscope		Open		RR (95% CI)	z- value	P- value	Weight
	Total	%	Total	%				
Trashvili et al., 2011	24	0.0%	28	3.6%	0.39 (0.02–9.07)	0.590	0.555	17.5%
Saber et al., 2015	60	6.7%	60	5.0%	1.33 (0.31–5.70)	0.388	0.698	82.5%
<b>Overall effect</b>					1.07 (0.29–4.02)	0.105	0.916	100%
<b>Heterogeneity</b>	<b>I<sup>2</sup></b>		0.000		<b>P-value</b>	0.485		

RR: Relative rate, CI: onfidene interval, \*Significant

**Figure (6): Forest plot for infection**

*Funnel plot for infection among could not be performed as the included studied were less than three.*

### 3- Operative Time:

Table (6) and figures (7) show that: **Operation duration** was reported in the two included studies. One study showed non-significant higher duration in laparoscope group and one study showed significant higher duration in laparoscope group.

There was significant heterogeneity among these studies. Thus, we performed the statistics using a random-effects model, and the results showed that **operation duration was not significantly higher in laparoscope group than in open group.**

**Table (6): Metanalysis for operation duration (minutes)**

Study	Laparoscope		Open		Difference Mean±SE (95% CI)	z- value	P-value	Weight
	N	Mean±SD	N	Mean±SD				
Trashvili et al., 2011	24	64.4±8.1	28	59.60±9.8	4.8±2.5 (-0.17–9.77)	1.892	0.058	52.2%
Saber et al., 2015	60	122.5±31.0	60	94.7.0±28.5	27.8±5.4 (17.1–38.5)	5.114	<0.001*	47.8%
<b>Overall effect</b>					15.8±11.5 (-6.7–38.3)	1.375	0.169	
<b>Heterogeneity</b>	<b>I<sup>2</sup></b>		93.196		<b>P-value</b>	<0.001*		

CI: onfidene interval, \*Significant



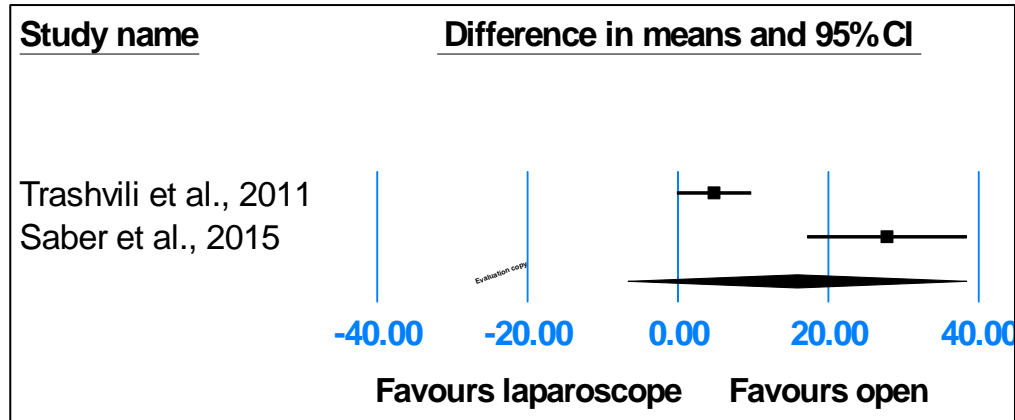


Figure (7): Forest plot for operation duration

*Funnel plot for operation duration among could not be performed as the included studied were less than three.*

## DISCUSSION

Hernia Repair is one of the most common surgical procedure performed all over the world whether primary repair or repair for recurrence. Therefore, it has been stated that 'the history of hernia repair is the history of surgery. The most common technique for inguinal hernia repair was originally an open, tissue-based suture repair, which eventually evolved to commonly use prosthetics (with various fixation devices of sutures, staples, tacks, and glue) for a tension-free repair with a significantly lower recurrence rate<sup>(1)</sup> and lower chronic pain after surgery<sup>(2)</sup>.

Laparoscopic repair of the inguinal hernia is becoming an increasingly popular method of herniorrhaphy with advantages such as reduction in postoperative pain and hospital stay, and the ability to undertake a simultaneous repair of symptomatic contralateral herniation. However, open repair can be performed under local anesthesia and is preferred by many surgeons.<sup>(4)</sup>

The choice of an appropriate surgical approach is more difficult in the treatment of a recurrent inguinal hernia than in the repair of a primary hernia. Currently, there is consensus that mesh should be used for recurrent repair, but there is no agreement about which technique, laparoscopic or open, should be considered the best treatment. There is a Shortage of research mainly about the treatment of choice of recurrent inguinal hernia after mesh repair, as the great part of patients included in the randomized trials had a

pure tissue repair at first operation. The clinical issue concerning the management of recurrent inguinal hernia needs further clarifications. For this reason, we performed this new meta-analysis comparing the outcome of laparoscopic and open tension-free repair.

On review of etiology of recurrent inguinal hernia, many causes were identified and classified into three categories. At first Factors related to the operation itself; most importantly the experience of the surgeon which effectively decreases the recurrence rate to 0.1% The recurrence rates in specialist hernia centers using the Shouldice technique—then the gold standard—were as low as 0.2%–2.7% with 100% follow-up of over 10 or more years<sup>(10)</sup>. Then presence of tension at the suture line creates area of ischemia and increase risk of recurrence. Infection would be responsible for 50% of recurrences as it leads to healing with scar and fibrosis that is unable to withstand the stress of the rise and fall of the intra-abdominal pressure and finally gives way to a recurrent groin hernia.<sup>(11)</sup> Also suturing material plays an important role as Synthetic absorbable sutures lose 50%–80% of their tensile strength within 14 days and disintegrate within a few weeks and so are unsuitable for hernia repair, therefore non absorbable suture material is preferred for inguinal hernia repair. Other two categories include general and local factors for recurrence such as; general condition of the patient, smoking, chronic cough, size of the hernia, type of the mesh used.

Our study aimed to compare the outcome of Open and laparoscopic mainly Transabdominal Preperitoneal (TAPP) repair of recurrent inguinal hernia regarding primary outcome such as recurrence and chronic pain and secondary outcome such as pain scores, wound infection, and operative time by including prospective randomized controlled studies carried out during 10 years period. A systematic review of literature was performed to find all studies related and the search was conducted using the following electronic data bases: PubMed and Science direct. The PRISMA flowchart for systematic search and selection of article for review was used and the resultant five studies were included in this Meta-analysis.

Regarding the primary outcome; **Recurrence** were reported in four out of the five studies one study “12” showed significant lower risk in laparoscope group and three studies showed non-significant lower risk in laparoscope group. and the results showed that **recurrence** was significantly lower risk among laparoscope than in open. The lower re-recurrence rate after laparoscopic repair has been related to the covering of all defects of the myopectineal orifice with a mesh. (13).

Chronic pain was reported in the four included studies. One study “**Bignell et al., 2012**” (14) showed non-significant higher risk in laparoscope group taking in consideration that the incidence of chronic groin pain after TAPP was higher, but the severity of pain in this group was less compared with open. One study “**Trashvili et al., 2011**” (15) showed non-significant lower risk in laparoscope group and two studies “**Saber et al., 2015 & Yang et al., 2018**” (16),(17) showed significant lower risk in laparoscope group. The laparoscopic approach reduces the risk of the injury to the ileo-inguinal and ileo-hypogastric nerves by approaching the recurrent hernia from the posterior preperitoneal space (18). The results showed that **chronic pain** was not significantly lower risk among laparoscope than in open.

Regarding secondary outcome; **Postoperative Pain score** Was reported in the two included studies. The two studies “**Bignell et al., 2012 & Saber et al., 2015**” (14),(16) showed significant lower pain in laparoscope group. The results showed that **Postoperative Pain score** Was significantly lower in laparoscope group than in open group.

**Infection** was reported in the two included studies. One study “**Saber et al., 2015**” (16) showed non-significant higher risk in laparoscope group and one study “**Trashvili et al., 2011**” (15) showed non-significant lower risk in laparoscope group. The results showed that **Infection** were not significantly different among laparoscope and open.

**Operation duration** was reported in the two included studies. One study “**Trashvili et al., 2011**” (15) showed non-significant higher duration in laparoscope group and one study “**Saber et al., 2015**” (16) showed significant higher duration in laparoscope group. The results showed that the main disadvantage of laparoscopic repair has been the duration of the operation as the mean operative time was longer in the laparoscopic operations, However the difference in **operation duration** was statistically significant.

In 2012 a similar a meta-analysis of randomized controlled trials comparing Laparoscopic or Lichtenstein repair for recurrent inguinal hernia was carried out by **J. Yang et al.**(17) showed that all five trials reported the rates of recurrence after recurrent inguinal hernia repair. There was no significant difference between the laparoscopic and Lichtenstein groups (14/221 (6.3%) versus 19/206 (9.2%). Four trials reported the presence of chronic pain. Significantly fewer patients with chronic pain were observed in the laparoscopic group compared with the Lichtenstein group (11/196 (5.6%) versus 28/181 (15.5%). Four trials reported wound infections after recurrent inguinal hernia repair. A comparison of wound infection rates between groups showed that the incidence was significantly lower after laparoscopic techniques that after the Lichtenstein repair (2/196 (1.0%) versus 8/181 (4.4%). The study concluded that the laparoscopic approach to the treatment of recurrent inguinal hernia is superior to the Lichtenstein hernioplasty in some aspects that affect patient satisfaction.

In 2014 another Meta-analysis and review of prospective randomized trials comparing laparoscopic and Lichtenstein techniques in recurrent inguinal hernia repair was performed by **A. Pisanu et al.** (19) Showed that the recurrence rate was lower in the laparoscopic group (8.3%) than in the anterior open one (11.6 %), but this difference was not statistically significant. The meta-analysis of chronic inguinal pain showed

significant difference between the two approaches. Indeed, the prevalence of chronic pain was 9.2% in the laparoscopic approach vs. 21.5 % in the anterior open approach. Mean operative time was significantly longer in the laparoscopic group than in the anterior open group (62.9 vs. 54.2 min). Data about postoperative pain evaluation were impossible to meta-analyze because only one study reported the results assessed by VAS score from 0 to 10. The prevalence of surgical site infection was 1.0 % in the laparoscopic group vs. 4.4 % in the anterior open group. However, this difference was not statistically significant. No other differences were found. The study concluded that Laparoscopy showed reduced chronic inguinal pain and an earlier return to normal daily activities but significantly longer operative time. Despite the expected advantages, the choice between laparoscopy and other techniques still depends on local expertise availability. Only dedicated centers are able to routinely offer laparoscopy for recurrent inguinal hernia repair.

According to our study the main significant difference of the outcome is related to decrease of recurrence risks and post-operative pain scores for the favor of the laparoscopic approach. Despite the expected advantages, the current choice between laparoscopy and other techniques in the management of a recurrent inguinal hernia still depends on local expertise availability.

## CONCLUSION

Both laparoscopic and open tension-free techniques appear to be effective for recurrent inguinal hernia repair with comparable outcome of interest. Drawing definitive conclusions about the better result of laparoscopy in reducing chronic inguinal pain is not easy because it must be verified by a longer-term follow up. Education, training and experience can shorten the operative time of laparoscopy.

The main advantage of the laparoscopic approach is decreasing the risk of recurrence and post-operative pain scores. No significant difference of outcome regarding chronic pain, site infection or operative time.

Based on the previous, whenever the expertise is available choosing the laparoscopic approach will give the patient advantage of less post-

operative pain and decreasing the risk of recurrence.

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