Original Article

Comparision Of Extraperitoneal Space Creation By Balloon Method V/S Direct Method In Laparoscopic Total Extraperitoneal Repair Of Inguinal Hernia

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Abstract

Aim: The aim of study is to compare advantages and disadvantages between two methods of extraperitoneal space creation for laparoscopic TEP repair of inguinal hernia.
Methods: The Prospective interventional study was conducted from October 2018 to November 2019at SSG Hospital, Vadodara. A total 50 patients of inguinal hernia taken for laparoscopic TEP repair, among them patients were divided in two groups by envelope method of randomization. Extraperitoneal space created by Conventional Balloon Device method.Extraperitoneal space created by direct method(dissection).
Results: In direct method group in 3 case Laparoscopic TEP converted to open hernioplasty due to poor visibility. In balloon method group no Laparoscopic TEP case converted to open.
Conclusion: As there is no significant difference in intraoperative and post operative complications between direct method and balloon method for extraperitoneal space creation in laparoscopic TEP repair of inguinal hernia, both methods are safe and equally effective.

Keywords: Inguinal hernia, Laparoscopic transabdominal preperitoneal repair (TAPP), Totally extraperitoneal repair (TEP), Recurrence, Chronic pain, Trial sequential analysis.

INTRODUCTION

Inguinal hernia is the most prevalent surgical disease in clinical practice. Laparoscopic inguinal hernia repair has been shown to be slightly superior to open approaches. Recent modifications in laparoscopic technique may improve the totally extraperitoneal repair (TEP) results.

The laparoscopic approach is based on the principle of tension-free repair, which has been well established by open operation of Nyhus and Stoppa. The greater availability of space in the extraperitoneal approach facilitates the insertion of a much bigger mesh.

The total extraperitoneal approach is the method of choice in the laparoscopic repair of the inguinal hernia. It is technically a difficult procedure and creation of extra peritoneal space with the help of balloon is helpful in the learning curve.[1]

There have been several innovations in technique and instruments to make it technically easier and to lower the cost of operation. By using a homemade balloon, non disposable ports have made the technique cost-effective.[2]

The totally extraperitoneal procedure (TEP) combines the advantages of tension-free mesh reinforcement of the groin with those of laparoscopicsurgery, reduces postoperative pain and shortens recovery time while avoiding the need for a trans-abdominal approach. The establishment of this technique by Dulucq in Europe may be considered a logical furtherdevelopment of total extra peritoneal hernia repair (TEP).[3]

However there are different method for approach to preperitoneal space:

1. Conventional balloon method
2. Dulucq method (Veress needle method).
3. Direct method (dissection)

MATERIALS & METHODS:

The Prospective interventional study was conducted from October 2018 to November 2019at SSG Hospital, Vadodara. A total 50 patients of inguinal hernia taken for laparoscopic TEP repair, among them patients were divided in two groups by envelope method of randomization. In 25 patients extra peritoneal space was created by balloon method and in 25 patients extra peritoneal space was created by direct method.

INCLUSION CRITERIA :

All patients of uncomplicated inguinal herniaundergoing laparoscopic total extraperitoneal inguinal hernia repair.

EXCLUSION CRITERIA :

1. Patients unfit for general anesthesia.
2. Age <18 years.
3. Complicated inguinal Hernia. (Irreducible, Obstructed,Strangulated)
4. Previous abdominal and hernia surgery.
5. Local skin infection.

We recorded all the observation in operative procedure during all steps for uniformity of study.A written informed consent was obtained.

In all 50 patients laparoscopic TEP repair done using balloon and direct method for extraperitoneal space creation. Complication during operation noted if it was observed. Total time for laparoscopic extraperitoneal space creation was noted in both group and total duration of operation was also noted.

The statistical analysis used was**,**Chi-Square Test &Independent t test.

RESULTS

All cases underwent detailed preoperative assessment; their preoperative findings, intraoperative and postoperative complications were meticulously recorded as per protocol. The findings were tabulated and the following observations were made.

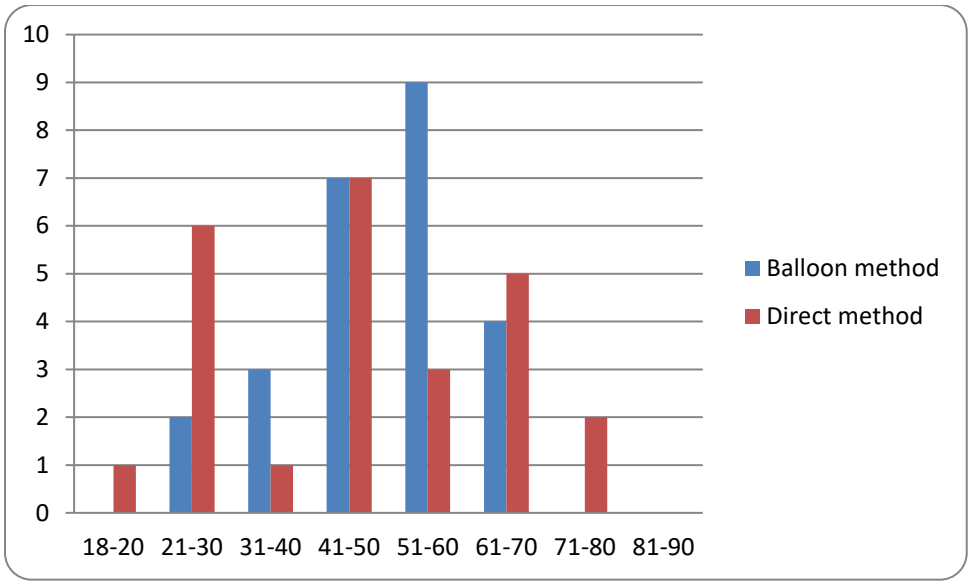

Figure 1: Age Distribution of Patients Studied

The mean age of patient in Balloon method group was 49.60±12.63 years (Range from 18-90 years) and Direct method group was47.88±17.08years (Range from 18-90 years).

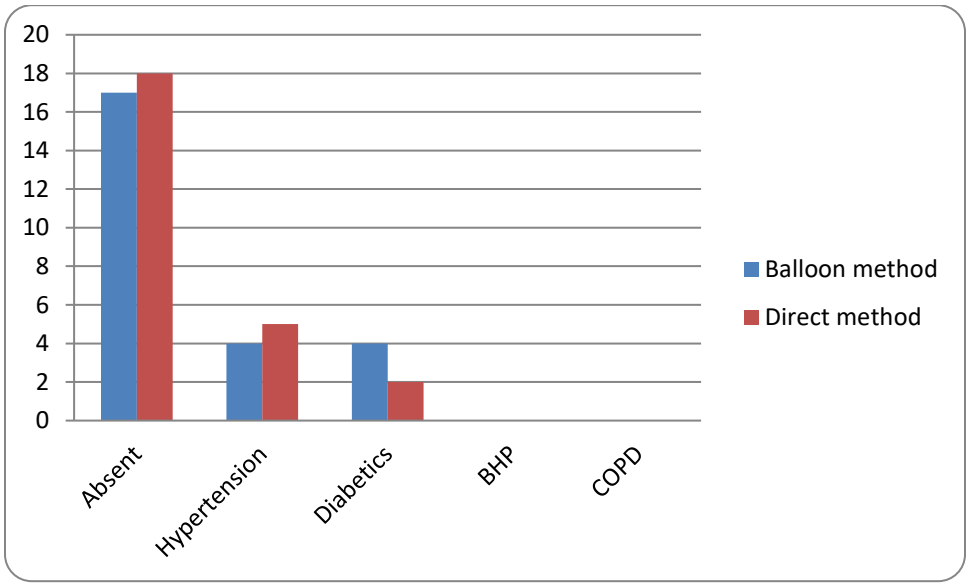

Figure 2 : Associated Disease of Patients Studied

In the **Balloon method** group, **32%** had associated diseases (4 patients with hypertension,4 diabetic).

In the **Direct method**group, **28%** had associated diseases (5 patients with Hypertension, 2 patient with diabetes)

Table: Comparison of Time taken for extraperitoneal space creation (Minutes) Between the balloon method and Direct method Group

Duration (in min)	Balloon method (n=25)		Direct method (n=25)	
	No	%	No	%

5-10	11	44	1	4
11-15	14	56	9	36
16-20	0	20	12	48
21-25	0	0	3	12
Mean +SD	11.56±2.14 minute		16.88±3.51 Minute	

The mean time taken for extraperitoneal space creation with balloon method in Laparoscopic TEP repair was 11.56±2.14 minute.

The mean time taken for extraperitoneal space creation with direct method in Laparoscopic TEP repair was 16.88±3.51 minute.

Time for extraperitoneal space creation was defined as time from first skin incision to 3 port placement in minute.

Table : Duration for extra peritoneal space creation

Operative time	**Balloon method (n=25)**	**Direct method (n=25)**
Average Duration	11.56±2.14 minute	16.88±3.51minute
Inference	Time for extra peritoneal space creation by balloon method was significantly less with statistical significance of t=-6.461; p=<0.0001**	

Total time taken for extra peritoneal space creation in laparoscopic TEP repair with Balloon method was significantly less with statistical significance of t=-6.461; p=<0.0001.

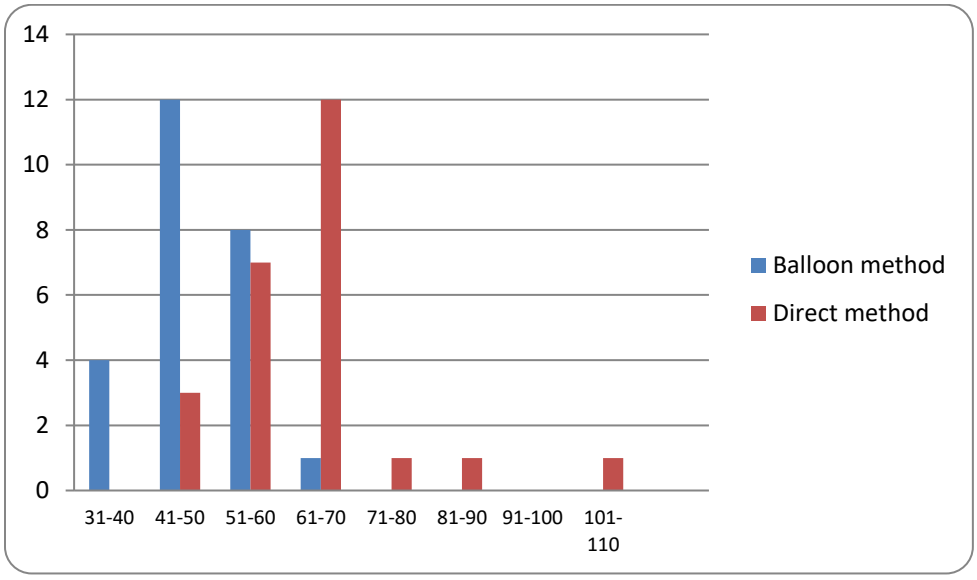

Figure: Comparison of total Operative Time (Minutes) Between the Balloon And Direct method Group

Average total operative time for laparoscopic TEP repair with balloon method was 48.72±7.55 minute.

Average total operative time for laparoscopic TEP repair with direct method was 63.92±12.63 minute.

Table : Total Operative Time (Minutes)

Operative time	Balloon method (n=25)	Direct method(n=25)
Average Duration	48.72±7.55 minute	63.92±12.63 minute
Inference	Total operative time was statistically significant between two methods with t = -5.17 and p =<0.0001	

Total operative time of laparoscopic TEP repair with direct method of extra peritoneal space creation was less than balloon method of extra peritoneal space creation with statistically significance between two methods with t = -5.17 and p =<0.0001.

Table - Conversion to open method in our Study

Conversion to open method	Balloon method (n=25)	Direct method (n=25)
Yes	0	3
Inference	Conversion to open method was not associated with the use of two methods for extraperitoneal space creation.	

In direct method group in 3 case Laparoscopic TEP converted to open hernioplasty due to poor visibility.In balloon method group no Laparoscopic TEP case converted to open.

DISCUSSION

Laparoscopic surgery, which was designed to reduce the surgical stress and complications associated with large incisions, has been shown to improve short-term outcomes without compromising long term results and is gaining popularity in various kinds of surgical procedures.

Since Ferzli et al. reported the first Laparoscopic TEP inguinal hernia repair in 1992, it has also proven to be safe and effective and laparoscopic TEP repair has been accepted as a standard alternative to the conventional open procedure. Although it has been associated with well-known advantages of laparoscopic surgery such as less pain and faster recovery, the widespread dissemination of laparoscopic TEP repair has been hampered by technical difficulties and a steep learning curve.[4]

A prospective interventional study with 25 patients undergoing Laparoscopic TEPrepair in which balloon method used for preperitoneal space creationand 25 patients undergoing Laparoscopic TEP repair in which direct method used for preperitoneal space creation was undertaken to study the efficacy based on total time taken for preperitoneal space creation,intraoperative complication,post operative complication, total duration of operation, post operative pain .

AGE AND GENDER DISTRIBUTION

All the patients in our study were males. It suggest that inguinal hernia is less common in female in general population.

In our study mean age of patients in Balloon method group was 49.60years and in Direct method group was 47.88 years.

Misra MC, Kumar S. et al[5], in their study of Laparoscopic TEP repair with balloon method There were 55 males and 1 female, with an average age of 49 years.

Abbasi, Mujeeb Rehman et al[6], in this study the average age was 43.6 years; ranging between 17 to 64 years.

Florin mihăileanu, Stefan Chiorescuet al[7], age of patients was in range of 19-74 years with mean age of 49 years.

It suggests that most patients in our study group was male between age group of 40-70years.

TYPE OF INGUINAL HERNIA

In our study, In Balloon method group patients with direct incomplete inguinal hernia was 44%cases and indirect incomplete was 56% cases.

In direct method group patients with direct incomplete inguinal hernia was 44% and indirect incomplete is 56% cases.

SIDE OF INGUINAL HERNIA

In our study in Balloon method group there were

- 14 (56%) right sided inguinal hernias
- 8 (32%) left side inguinal hernias
- 3 (12%) bilateral inguinal hernias

In Direct method group there were:

- 11 (44%) right sided inguinal hernias
- 7 (28%) left sided inguinal hernias
- 7 (28%)bilateral inguinal hernias

Abbasi, Mujeeb Rehman et al[6], they had 20 male patients for their study. Only 2 patients (10%) had bilateral groin hernia, 4 patients (40%) had direct inguinal hernia in balloon method; 5 patients (50%) had direct hernia in non balloon method.

Muhammad Hanif, Anis Ahmed et al,the study included 87 patients undergoing inguinal hernia repair using balloon method of TEP, Majority of hernias i.e. 48 (55.2%) were on the right side, 20 (23%) on the left and remaining 19 (21.8%) were bilateral. 74 (85%) were primary inguinal hernia repairs and 13 (15%) were on recurrent cases.

OPERATIVE TIME FOR EXTRAPERITONEAL SPACE CREATION

In our study, the mean time for extraperitoneal space creation in laparoscopic TEP repair by balloon method was **11.56 minutes.**

The mean time for extraperitoneal space creation in laparoscopic TEP repair by Direct method was **16.88 minutes.**

Hence the overall mean time for extraperitoneal space creation in laparoscopic TEP repair with balloon method was significantly less than direct method.

Time for extra peritoneal space creation by balloon method was significantly less with statistical significance of t=-60461; p=<0.0001.

There was no comparing study available which compare the time taken for extraperitoneal space creation between balloon method and direct method.

TOTAL OPERATIVE TIME

The mean total operative time taken in laparoscopic TEP repair with balloon method was **48.72minutes**.

The mean total operative time taken in laparoscopic TEP repair with direct method was **63.92minutes.**

Total operative time of laparoscopic TEP repair with balloon method of extra peritoneal space creation was less than direct method of extra peritoneal space creation with statistically significance between two methods with t = -5.17 and p =<0.0001.

S. Bringman et al A randomized prospective multicenter study,The mean operation time was 55 min in the group with the balloon (total 161 patients) and 63 min in the group without the balloon (p=0.004)(total 161 patients)[8].

Ah Young Kang, M.D., Sung Ryol Lee, et al,Sungkyunkwan University School of Medicine, Seoul, Korea, a retrospective analysis of a consecutive series of inguinal hernia repairs performed by a single surgeon in Hospital between April 2008 and April 2012.Of the 128 patients, whose full-length video recordings were available, 57 were

in the balloon dissection group and 71 were in the plain dissection group.Mean operation time was shorter in the plain dissection group (57.7 vs. 45.6 min, $p < 0.001$).[9]

Jaspal DP et al,Department of Surgery, M.M.I.M.S.R, Mullana, Ambala India, Between January 2014 and September 2015, consecutive 50 cases of totally extra-peritoneal repair (TEP) were done using a homemade balloon for creating the extra peritoneal space the mean total operation time was 50 min.[10]

Abbasi, Mujeeb Rehman et al, the mean operation time was 55 min (45-100) in the group with the balloon and 73 min (50-120min) in the group without the balloon ($p = 0.004$).[6]

COMPARISON OF INTRAOPERATIVE COMPLICATION AND COMPLICATIONS DURING EXTRA PERITONEAL SPACE CREATION.

In TEP with balloon method Intraperitoneal CO_2 leak was not observed, similarly in TEP with Direct method intraperitoneal CO_2 leak was not observed.

In TEP with balloon method visible peritoneal tear was not observed, while in TEP with Direct method visible peritoneal tear was in 2 patients (8%).

In TEP with balloon method subcutaneous emphysema was in 1 patients (4%) ,while in TEP with direct method subcutaneous emphysema was in 2 patients (8%).

In TEP with balloon method space inadequacy was in 1 patients (4%),while in TEP with direct method space inadequacy was in 3 patients (12%).

Incidence ofVisible peritoneal tear, Space inadequacy and Subcutaneous emphysema like complications were more in direct method group but not statistically significant.

Misra MC, Kumar S. et al[5], in their study of Laparoscopic TEP repair with balloon method, Creation of extraperitoneal space was considered as satisfactory in majority of patients (94.6%) with satisfactory anatomical delineation. Peritoneal breach was noticed during dissection in 36 (64.3%) patients.

Abbasi, Mujeeb Rehman et al[6], peritoneum was breached in 5 (50%) patients with telescopic dissection. One patient (10%) with bilateral groin hernia in telescopic dissection group had large tear in peritoneum converted to TAPP while other group normal.

Florin mihăileanu, Stefan Chiorescuet al[7], in this study of laparoscopic TEP repair with balloon method in 7 cases the accidental lesion of the peritoneum with pneumoperitoneum occurred. One case needed conversion to the Lichtenstein technique due to the loss of the work camera. In 1 case they had a hemorrhage from the level of the epigastric vessels.

COMPARISON OF POST OPERATIVE COMPLICATION.

The complications observed in our study were as follows:

	Balloon method	Direct method
Surgical emphysema	0 cases	1 cases
Port site infection	0 cases	2 cases
Seroma	0 cases	0 cases

Surgical subcutaneous emphysema regressed by 2nd postoperative day, without surgical intervention. Total 2 cases of port site infection was treated with extended oral antibiotics and within 5 days wound was normal.

Misra MC, Kumar S. et al[5], The incidence of scrotal edema was significantly higher in non balloon method as compared with balloon method group ($p < 0.01$). Of the patients, 17.9% developed seroma in balloon method group versus 64.3% in non balloon method group ($p < 0.001$).

Abbasi, Mujeeb Rehman et al[6] study, the incidence of scrotal edema/seroma was greater in telescopic dissection then balloon method. 40% patient in telescopic dissection group developed seroma while 0nly 1 (10%) patient with bilateral groin hernia in balloon developed seroma.

In direct method group in 3 Laparoscopic TEP case converted to open hernioplasty due to space inadequacy and poor visibility.In balloon method group in no case of laparoscopic TEP was converted to open.Muhammad Hanif, Anis Ahmed et al[11], there were 4 conversions (4.6%). All were converted to Lichtenstein hernioplasty. Reasons for conversion were: problems with adhesions and local anatomy in 2 (2.3%) cases, peritoneal tear in 1 (1.15%) and bleeding from epigastric vessels in 1 (1.15%).

CONCLUSION

In conclusion, Time for extra peritoneal space creation by balloonmethod is significantly less as compare with direct method for extraperitoneal space creation in laparoscopic TEP repair of inguinal hernia.

Total operative time of laparoscopic TEP repair with balloon method of extra peritoneal space creation was less than laparoscopic TEP repair with direct method of extra peritoneal space creation with statistical significance between two methods.

Incidence ofVisible peritoneal tear and Subcutaneous emphysema like complications were more in Direct method group but not statistically significant .

Incidence of postoperative complication like subcutaneous emphysema, port site infection between two methods of extraperitoneal space creation was not statistically significant.

So, balloon method is homemade balloon device for extraperitoneal space creation in laparoscopic TEP repair of inguinal hernia, with less time for extraperitoneal space creation and ease of it.

As there is no significant difference in intraoperative and post operative complications between direct method and balloon method for extraperitoneal space creation in laparoscopic TEP repair of inguinal hernia, both methods are safe and equally effective.

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