



## Surgery

## INDIGENOUS BALLOON VERSUS TELESCOPIC DISSECTION FOR EXTRAPERITONEAL SPACE CREATION IN TEP: A RANDOMISED COMPARATIVE TRIAL.

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**ABSTRACT** Among different laparoscopic technique, TEP has advantage of non violation of coelomic cavity hence very less chance of visceral injury and adhesion formation. TEP has long learning curve probably because of constraint of working space and unfamiliar preperitoneal anatomy and surrounding major vessels. Dissection to create pre-peritoneal space can be done directly with telescope or with help of balloon technique.  
**Methods-** We used an indigenous balloon made by tying the two cut piece of middle finger of latex glove tightly onto the tip of the suction cannula with silk to create the extraperitoneal space  
**Results-** results were compared in terms of operative times, peritoneal breach, post operative pain, seroma formation and scrotal edema. It was observed that results were definitely better with balloon dissection in all parameter studied and were significantly better on statistical analysis in terms of Post operative pain, peritoneal breach and seroma formation.

**KEYWORDS :** Balloon dissection, Telescopic dissection, TEP

Laparoscopic approach for hernia has evolved rapidly over the past two decade and accounts for about 20% of hernia surgery<sup>[1]</sup> The first laparoscopic inguinal hernia repair was described by Ralph Ger in the year 1982 and over recent years it has gained popularity<sup>[2]</sup>. Among different laparoscopic technique, TEP has advantage of non violation of coelomic cavity hence very less chance of visceral injury and adhesion formation<sup>[3]</sup>. TEP has long learning curve probably because of constraint of working space and unfamiliar preperitoneal anatomy and surrounding major vessels<sup>[4]</sup>. Dissection to create pre-peritoneal space can be done directly with telescope or with balloon technique. Balloon dissection is considered essential, easier, quicker, and safe to create the extra-peritoneal space<sup>[5-8]</sup>.

Our study is designed to compare the efficacy and outcome of indigenously made balloon dissection versus direct telescopic dissection to create extra-peritoneal space for performing TEP repair

### Material and methods

The study was conducted in the Department of General Surgery of Post graduate institute of medical education and research Dr Ram Manohar Lohia Hospital New Delhi, between 1<sup>st</sup> August 2015 to 31<sup>st</sup> March 2017. A total 63 patients (30 - telescopic dissection and 33 - balloon dissection) of unilateral inguinal hernia were included in this study with. The study was duly approved by Departmental Research Committee and Institutional Ethics Committee of our institute. The Study design were Randomized comparative trial to avoid any biases, and method of randomization were done by Computer based electronic randomization taken from <http://www.randomization.com>.

The INCLUSION criteria were Patients aged 18 years and above with primary unilateral inguinal hernia. The EXCLUSION criteria were Patients with complications of inguinal hernia like irreducible, obstructed and strangulated hernia. Patients with previous lower abdominal surgery and those refused to give consent were excluded from the study

### METHODOLOGY

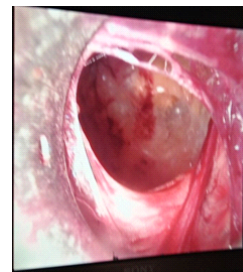
Detailed history, clinical examination and all relevant investigation were performed and enrolled for study after detailed written informed consent

### TECHNIQUE:

In our study, We used an indigenous balloon made by tying the two cut piece of middle finger of latex glove tightly onto the tip of the suction cannula with silk. The Patency or any leak from the side of the glove

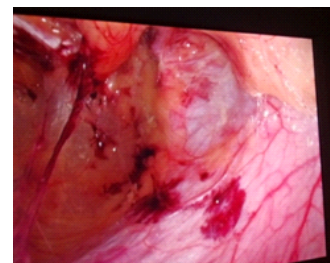
finger was checked using normal saline before introducing it into extra-peritoneal space.

The balloon prepared was then introduced through umbilical port into the extra-peritoneal space and inflated with up to 200 ml normal saline to create the working extra-peritoneal space and left for two minutes to ensure haemostasis before being aspirated and cannula withdrawn. Carbon dioxide insufflations were done into the extra-peritoneal space to achieve extra-peritoneal pressure of upto 18-20 mmHg. Two additional 5-mm ports were introduced under vision: the first 2 cm above the pubic symphysis in the midline and the other mid way between the two ports



**Fig 1- Space creation by Indigenous balloon**

In direct telescopic dissection, initial extra-peritoneal space was created by introducing a 10-mm 30 degree telescope in infra-umbilical region and moving it gently side to side to separate the extra peritoneal loose areolar tissue. The rest of the procedure after that like Port placement, and further dissection upto mesh placement were essentially the same in both the group.



**Fig2- Space creation by Telescopic dissection**

All the patient were assessed Intra and postoperative period in terms of duration of surgery, peritoneal breach, post operative pain, seroma formation and scrotal edema development.

All patients followed up for two weeks after the patient is discharged from hospital. Data was collected in MS EXCEL spreadsheet and analyzed using statistical software package SPSS v22.0 method. Categorical variables were presented in number & percentage (%) and continuous variables were presented as mean  $\pm$  SD. Normality of data was tested and if the normality was rejected then non parametric test was used. Continuous variables were compared using t-test /Mann-Whitney test and ordinal/nominal data was compared using Chi square/Fisher's test. p value <0.05 was taken as significant.

### Observations

A total of 63 patients satisfying the inclusion criteria were included in the study, of which 30 in telescopic dissection group and 33 in balloon dissection group. Mean age of patient belonging to balloon dissection group is 39.45 years and that of telescopic dissection is 39.87 years.

Out of 63 patients, 24 (38.09%) had left sided inguinal hernia and 39 (61.90%) had right sided inguinal hernia. The chi square value was 0.050 and the p-value was 0.824 and the difference is not statistically significant. 19 patients (30.15%) had direct hernia and 44 (69.84%) had indirect hernia. Chi-square analysis suggests that there was no statistical difference in distribution of type of hernia in both the group. Mean operative time was 59.30 minutes in balloon dissection group and 70.13 minutes in telescopic dissection group. The t-test analysis suggests that there was significantly greater operative time in subjects included in the telescopic group with p-value <0.05.

**Table 1- Compare the outcome of the two group**

outcome	Balloon dissec.,	Telescopicdissec.	P-value
Operative time	59.30	70.13	<0.001
Peritoneal breach	5/33	12/30	0.026*
Pain ( at 6 hr)	29.55(meanrank)	34.70(mean rank)	0.243
Seroma ( 1st wk)	4/33	10/30	0.043*
Seroma( 2nd wk)	2/33	5/30	0.181
Scrotal edema	1/33	2/30	0.458

Peritoneal breach occurred in 5 patients (15.1%) of balloon dissection group and 12 patients (40%) of telescopic dissection group. Chi square analysis suggests that there were significantly more incidences of peritoneal breach in telescopic group of subjects than balloon group. The chi square value was 4.925 and the p-value was <0.05.

No significant difference in pain on VAS scale was observed at 6<sup>th</sup> hour after surgery in two groups with the p-value >0.05.

Four patients (12.1%) in balloon dissection group and ten patients (33.3%) in telescopic dissection group developed seroma within 1<sup>st</sup> Post operative week. Which continued till 2<sup>nd</sup> week in 2 patients in balloon group and 5 patients in telescopic group. Chi square analysis suggests that there was significantly higher incidence of seroma formation in the subjects undergone telescopic procedure than balloon one. The chi square value was 4.091 with the p-value <0.05.

Scrotal edema developed in 1 patient (3.03%) of balloon dissection group and 2 patients (6.66%) of telescopic dissection group. Chi square analysis suggests no significant difference in incidence of scrotal edema between the two groups with p-value was >0.05.

### DISCUSSION

Laparoscopic hernia repair has gained a good momentum in the last two decades, but yet to gain the recognition of gold standard technique. Among all the available technique (TEP, TAPP & IPOM), Total extra peritoneal (TEP) has become most common technique for inguinal hernia repair in last decade. It is preferred over other laparoscopic repair as sanctity of peritoneal cavity is maintained. It has benefit of both minimal access surgery as well as tension free repair.

Creation of extra-peritoneal space and finding correct plane for dissection is one of the main difficulties of this procedure which can be done with direct telescopic dissection as well as commercially available balloon dissector which increases the cost of procedure<sup>[9]</sup>. Instead of commercially available balloon, we prepared a very low cost indigenous balloon made from surgical latex glove. Balloon

dissection is considered easier, quicker, and safe to create the extra-peritoneal space<sup>[13-16/5-8]</sup>. The most important predictor of laparoscopic good hernia repair is the creation of working space so that the hernia sac can be identified and dissected, all defects identified, and a proper size of mesh placement to cover all the defects.

Our study was to compare the result of direct telescopic dissection with balloon dissection (low cost indigenous balloon) in terms of operating time, ease of surgery in terms of peritoneal breach and post operative complications like post operative pain, seroma formation, scrotal edema.

Peritoneal breach: It is one of the common causes for conversion of TEP to TAPP. Breach in peritoneum leads to pneumoperitoneum hence decreases the working space. The patient with indirect hernia and a large hernia sac has more chance of peritoneum breach which may need conversion of TEP to TAPP. Bringman<sup>[10]</sup> reported an incidence of 2.5% of conversions of TEP to TAPP in his study in the group with balloon dissection while it was 10.6% in group with direct telescopic dissection due to peritoneal breach. Intraoperative telescopic laceration ranges from 10% to 64% in different series.<sup>[11,12]</sup> Peritoneal tear in 57.1% of patients in the balloon dissection group as compared to 71.4% of patients in the direct telescopic dissection group was seen<sup>[10]</sup>. In our study peritoneal breach occurred in 5 patients (15.1%) of balloon dissection group and 12 patients (40%) of telescopic dissection group. On statistical analysis the difference in incidence of peritoneal breach proved significant with P value <0.05

### TIME TAKEN FOR SURGERY:

It was calculated as mean time taken from port site incision to port site skin closure. In our study mean operative time were 59.30 minutes in balloon dissection group and 70.13 minutes in telescopic dissection group. The t-test analysis suggests that there was significantly greater operative time in subjects included in the telescopic group of subjects as the p-value was <0.05. it is most probably due to better space creation in the balloon group compared to Telescopic one.

Similar result was found in study carried by Fiennes et al<sup>[13]</sup> who used the balloon dissector and felt that it provides a reliable access and good preliminary dissection with a saving in operative time. While in study carried by Bringman and M C mishra et al show no significant difference in operative time taken between these two groups.

**POST OPERATIVE PAIN:** Pain is one of the most common concerns after hernia surgery<sup>[14,15]</sup>. No significant difference in pain on VAS scale was observed at 6<sup>th</sup> hour after surgery in two groups with p value of .243 in our study. But the pain score on VAS was higher in telescopic group at 6 h after surgery in study done by M.C.Misra et al<sup>[9]</sup>. However multiple studies show various other factors like size of sac, age of patient are independent risk factors for pain<sup>[16]</sup>. It has been found from studies that young patients feel more pain as compared to elders on VAS scale assessment of pain.

**INCIDENCE OF SCROTAL EDEMA:** Scrotal edema is one of well known complication of both open as well as laparoscopic hernia repair. In our study Scrotal edema developed in 1 patient (3.03%) of balloon dissection group and 2 patients (6.66%) of telescopic dissection group. Chi square analysis suggests no significant difference in incidence of scrotal edema between the two groups. The chi square value was 0.498 and the p-value was >0.05.

The incidence of scrotal edema was significantly higher in the telescopic dissection group as compared with the balloon dissection in study done by M.C.Misra et al. Various other confounding clinical factors associated with scrotal edema formation were old age, large hernia defect, extension of the hernia into scrotum, and presence of distal indirect sac in a study conducted by Lau et al<sup>[12]</sup>.

**SEROMA FORMATION:** Four patients (12.1%) in balloon dissection group and nine patients (30 %) in telescopic dissection group developed seroma in 1<sup>st</sup> post operative week. Two patients(6.06%) of balloon dissection group and five patients(16.6%) of telescopic dissection group had seroma continued in 2<sup>nd</sup> post operative week. On statistical analysis there was significantly higher incidence of seroma formation in the subjects undergone telescopic procedure than balloon with p-value <0.05. The incidence of scrotal edema and seroma formation is less in balloon group is probably because of better space creation leading to less bleeding hence less

seroma formation.

In our study overall seroma formation was more in direct telescopic dissection group as compared to balloon aided dissection group which is comparable to study done by M.C.Misra *et al* which shows seroma formation rate was significantly higher in telescopic dissection group<sup>19</sup>. Susmalian *et al.*<sup>17</sup> observed that size of seroma was related to size of sac during laparoscopic repair of hernia. Jehaes *et al.*<sup>18</sup> suggested that removing the entire sac in the case of indirect hernia repair or stapling the fascia transversalis to Cooper's ligament in case of direct hernia repair avoid cavity formation could avoid seroma formation.

## CONCLUSION AND RECOMMENDATION

The study finished with the conclusion that in balloon dissection for creation of working extra-peritoneal space in TEP, the operative time was significantly less and there is lesser incidence of peritoneal breach and seroma formation as compared to direct telescopic dissection group. A study with larger no. of cases is needed to further strengthen the findings and conclusion.

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