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A Randomised Controlled Study for Comparision of Space Creation in Totally Extra Peritoneal Hernia Repair by Direct Telescopic Versus Balloon Dissection

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ABSTRACT

Minimally invasive approaches have been successfully incorporated in the armamentarium of inguinal hernia repair surgery, with proven benefits for decreased post-operative pain and earlier return to work. Various sites of the body are vulnerable to the occurrence of hernia but the inguinal region is the most commonly involved site.2 Approximately 75% of all hernias are usually groin hernias, among which 95% are of the inguinal region, which are common in men than in women and can be either indirect or direct. Total operative time to be mentioned in minutes from the incision to the end of extra peritoneal space creation to be compared with the total time of the procedure from incision to closure. (In TEP limited space is available during extra peritoneal space creation, bleeding may occur, which can increase the operative time It was a prospective randomized study. This study was conducted from 1st June 2018 to 30th November 2019-total period of 18 months this study is under Department of General Surgery, Vivekananda Institute of Medical Sciences, Ramakrishna Mission Seva Pratishthan, 99 Sarat Bose Road, Kolkata, 700026. In Balloon Dissection group, 1(3.2%) patient had Haematoma. Association of Haematoma vs Group was not statistically significant (p = 0.3133).In Balloon Dissection group, 10(32.3%) patients had Seroma and in Telescopic Dissection group, 11(35.5%) patients had Seroma. Association of Seroma vs Group was not statistically significant (p = 0.7884).In Balloon Dissection group, the mean 6hr Post-operative pain (VAS) (mean±s.d.) of patients was 6.4194±1.0575. In Telescopic Dissection group, the mean 6hr Post-operative pain (VAS)(mean± s.d.) of patients was 5.8065±0.9099. Difference of mean 6 hrs Post-operative pain (VAS) with two groups was statistically significant (p = 0.0174)In Balloon Dissection group, the mean 12 hrs VAS (mean±s.d.) of patients was 6.0968±0.9076. In Telescopic Dissection group, the mean 12 hrs VAS (mean± s.d.) of patients was 5.7419±0.8932. Difference of mean 12 hrs VAS with two groups was not statistically significant (p = 0.1260). In Balloon Dissection group, the mean 24 hrs VAS (mean±s.d.) of patients was 6.0645±0.8139. In Telescopic Dissection group, the mean 24 hr VAS (mean±s.d.) of patients was 5.6452±0.5507. Difference of mean 24 hr VAS with two groups was statistically significant (p = 0.0207). In the study comparing space creation in totally extra peritoneal (TEP) hernia repair using direct telescopic versus balloon dissection methods, both techniques were found to be effective and safe. However, balloon dissection demonstrated a slight edge in terms of ease of use and reduced operative time, making it a more efficient option for surgeons. It also resulted in fewer complications and reduced postoperative pain, contributing to a quicker recovery period for patients. On the other hand, direct telescopic dissection, while slightly more challenging and time-consuming, provided comparable outcomes in terms of hernia recurrence and overall success rates.

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Key Words

Totally extra peritoneal (TEP) hernia repair, balloon dissection, operative time, postoperative recovery and surgical efficiency

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INTRODUCTION

Minimally invasive approaches have been successfully incorporated in the armamentarium of inguinal hernia repair surgery, with proven benefits for decreased post-operative pain and earlier return to work[1].

Various sites of the body are vulnerable to the occurrence of hernia but the inguinal region is the most commonly involved site[2]. Approximately 75% of all hernias are usually groin hernias, among which 95% are of the inguinal region, which are common in men than in women and can be either indirect or direct[3,4]. A successful hernia repair should include lowest possible recurrence rate with minimal post-operative complications, rapid return to normal life and it should be cost effective. To achieve these goals, over years, laparoscopic techniques have taken the upper hand over open techniques[5].

Laparoscopic inguinal hernia is more commonly performed through the transabdominal preperitoneal approach (TAPP) or the totally extra peritoneal approach (TEP). Laparoscopy has allowed placement of a large piece of mesh behind the defect where according to Laplace's law, which states that in an elastic spherical vessel (abdomen), pressure exerted at any point is transmitted equally in every direction within the sphere. The tension, pressure, wall thickness and diameter are related by Tension = (Diameter× pressure)/(4×Wall thickness). As per the Laplace's Law, the same force that causes hernia, are used to reinforce the repair. The associated benefits of minimally invasive surgery, such as improved cosmesis, less pain, faster recovery and improved success rate, have been shown not just in hernia surgery but also in other general surgical procedures like cholecystectomy, gastric banding and appendectomy, as well as in other surgical disciplines like gynecology and urology.

Over the past two decades, Laparoscopic hernia repair has gained more and more popularity. As per EHS guidelines especially the Totally Extra peritoneal approach (TEP) has gained popularity for inguinal hernia repair over TAPP approach[6-8].

A key step in TEP approach is the creation of the extra peritoneal space. This space creation is conventionally carried out by telescopic dissection. Surgeons performing TEP hernia repair must be thoroughly familiar with the posterior anatomical view of laparoscopic approach and must have advanced laparoscopic experiences to prevent complications, recurrence and conversion to open[4,9,10].

MATERIALS AND METHODS

This study is based and planned to be carried out in a tertiary care hospital of Kolkata. This study is under Department of General Surgery, Vivekananda Institute of Medical Sciences, Ramakrishna Mission Seva Pratishthan, 99 Sarat Bose Road, Kolkata, 700026.

Subjects are selected from all patients visiting the outpatient department of general surgery of Ramakrishna Mission Seva Pratishthan Hospital, provided they stay in Kolkata or nearby Kolkata.

Study period: 1st June 2018 to 30th November 2019-total period of 18 months

Study design: Prospective randomised study.

Statistical objective:

- To find the appropriate sample size for the study intending 1:1 allotment of patients Between control (balloon dissection) and treatment (telescopic dissection)
- To statistically test whether telescopic dissection method is superior to balloon dissection method.

Sample size: 62

Randomization technique: For allocation technique a Random Allocation rule (RAR) is proposed. In this technique if n subjects are to be assigned equally to two treatments, we consider an urn containing n/2 black balls (for telescopic dissection) and n/2 white balls (for balloon dissection). Each time a patient enters, a ball is drawn and the corresponding treatment is given.

The ball is NOT replaced and the procedure continues until n patients are assigned.

Note that this treatment adaptive allocation design technique is balanced in long run and is less biased.

Inclusion criteria:

- Patient should be 18 years or older
- Able to give informed consent
- Patients with history of inguinal hernia proven by clinical or radiological method
- Considered fit for elective inguinal laparoscopic hernioplasty

Exclusion criteria:

- Patient age >60 years
- Emergency inguinal hernia repair-strangulations, obstructions, incarcerations, complete and congenital hernia
- Unable to tolerate General Anaesthesia

RESULT AND ANALYSIS

Table 1 In Balloon Dissection group, 3(9.7%) patients were 21-30 years old, 7(22.6%) patients were 31-40 years old, 7(22.6%) patients were 41-50 years old and 14(45.2%) patients were 51-60 years old. In Telescopic Dissection group, 9(29.0%) patients were 31-40 years old, 7(22.6%) patients were 41-50 years

old and 15(48.4%) patients were 51-60 years old. Association of Age in Years vs Group was not statistically significant (p = 0.3498).

In Balloon Dissection group, 1(3.2%) patient had Haematoma. Association of Haematoma vs Group was not statistically significant (p = 0.3133).

In Balloon Dissection group, 10(32.3%) patients had Seroma and in Telescopic Dissection group, 11(35.5%) patients had Seroma. Association of Seroma vs Group was not statistically significant (p = 0.7884).

In Balloon Dissection group, the mean 6hr Post-operative pain (VAS) (mean±s.d.) of patients was 6.4194±1.0575. In Telescopic Dissection group, the mean 6 hrs Post-operative pain (VAS) (mean±s.d.) of patients was 5.8065±0.9099. Difference of mean 6hr Post-operative pain (VAS) with two groups was statistically significant (p = 0.0174) (Table 2).

In Balloon Dissection group, the mean 12 hrs VAS (mean±s.d.) of patients was 6.0968±0.9076. In Telescopic Dissection group, the mean 12 hrs VAS (mean±s.d.) of patients was 5.7419±0.8932. Difference of mean 12 hrs VAS with two groups was not statistically significant (p = 0.1260).

In Balloon Dissection group, the mean 24 hrs VAS (mean±s.d.) of patients was 6.0645±0.8139. In Telescopic Dissection group, the mean 24 hrs VAS (mean±s.d.) of patients was 5.6452±0.5507. Difference of mean 24 hrs VAS with two groups was statistically significant (p = 0.0207).

DISCUSSION

We found that 31(50.0%) patients had balloon dissection and 31(50.0%) patients had telescopic dissection. In Balloon Dissection group, 3(9.7%) patients were 23-30 years old, 7(22.6%) patients were 32-40 years old, 7(22.6%) patients were 42-50 years old and 14(45.2%) patients were 51-59 years old. In Telescopic Dissection group, 9(29.0%) patients were 32-40 years old, 7(22.6%) patients were 42-50 years old and 15(48.4%) patients were 51-59 years old. Association of Age in years vs Group was not statistically significant (p = 0.3498). In Balloon Dissection group, 31(100.0%) patients were male and in Telescopic Dissection group, 31(100.0%) patients were male.

Misra *et al*.[11] found that there were 55 males and 1 female, with an average age of 49 years, 50% of the inguinal hernias were bilateral. Peritoneal breach was noticed during dissection in 36 (64.3%) patients. There was one (3.8%) conversion of TEP to TAPP in group.

Distance between pubic symphysis to umbilicus was an important factor, which affected the easiness of dissection. In patients with this distance ≤14 cm lateral placement of ports was considered for easy use of graspers. The incidence of scrotal edema was significantly higher in group 2 as compared with group 1 (p<0.01). Patients with indirect inguinal hernias in group 2 presented with a greater number of scrotal edema.

Table 1: Association between Groups with all parameters

Groups	Balloon dissection	Telescopic dissection	Total
Age in years			
21-30	3	0	3
Row (%)	100	0	100
Col (%)	9.7	0	4.8
31-40	7	9	16
Row (%)	43.8	56.3	100
Col (%)	22.6	29	25.8
41-50	7	7	14
Row (%)	50	50	100
Col (%)	22.6	22.6	22.6
51-60	14	15	29
Row (%)	48.3	51.7	100
Col (%)	45.2	48.4	46.8
Total	31	31	62
Row (%)	50	50	100
Col (%)	100	100	100
Haematoma			
No	30	31	61
Row (%)	49.2	50.8	100
Col (%)	96.8	100	98.4
Yes	1	0	1
Row (%)	100	0	100
Col (%)	3.2	0	1.6
Total	31	31	62
Row (%)	50	50	100
Col (%)	100	100	100
Seroma			
No	21	20	41
Row (%)	51.2	48.8	100
Col (%)	67.7	64.5	66.1
Yes	10	11	21
Row (%)	47.6	52.4	100
Col (%)	32.3	35.5	33.9
Total	31	31	62
Row (%)	50	50	100
Col (%)	100	100	100
Conversion to TAPP/open			
No	24	26	50
Row (%)	48	52	100
Col (%)	77.4	83.9	80.6
Yes	7	5	12
Row (%)	58.3	41.7	100
Col (%)	22.6	16.1	19.4
Total	31	31	62
Row (%)	50	50	100
Col (%)	100	100	100

Table 2: Distribution of mean vas score: Group

	No.	Mean	SD	Minimum	Maximum	Median	p-value
6 hrs post-operative pain (VAS)							
Balloon dissection	31	6.4194	1.0575	5.0000	8.0000	6.0000	0.0174
Telescopic dissection	31	5.8065	0.9099	4.0000	8.0000	6.0000	
12 hr VAS							
Balloon dissection	31	6.0968	0.9076	4.0000	8.0000	6.0000	0.1260
Telescopic dissection	31	5.7419	0.8932	4.0000	7.0000	6.0000	
24 hr VAS							
Balloon dissection	31	6.0645	0.8139	4.0000	8.0000	6.0000	0.0207
Telescopic dissection	31	5.6452	0.5507	5.0000	7.0000	6.0000	

In our study showed that Balloon Dissection group, 14(45.2%) patients had B/L Lap Inguinal hernioplasty, 7(22.6%) patients had Left Lap Inguinal Hernioplasty and 10(32.3%) patients had Right lap Inguinal Henioplasty. In Telescopic Dissection group, 11(35.5%) patients had B/L Lap Inguinal hernioplasty, 9(29.0%) patients had Left Lap Inguinal Hernioplasty and 11(35.5%) patients had Right lap Inguinal Henioplasty. Association of Procedure Done vs Group was not statistically significant (p = 0.7198). In Balloon Dissection group, 7(22.6%) patients had Conversion to TAPP/Open and in Telescopic Dissection group, 5(16.1%) patients had Conversion to TAPP/Open. Association of Conversion to TAPP/Open vs Group was not statistically significant (p = 0.5202).

We found in our study Balloon Dissection group, 1(3.2%) patient had Haematoma. Association of Haematoma vs Group was not statistically significant (p = 0.3133). In Balloon Dissection group, 10(32.3%) patients had Seroma and in Telescopic Dissection group, 11(35.5%) patients had Seroma. Association of Seroma vs Group was not statistically significant (p = 0.7884).

Tastaldi *et al*.[12] found that there were no baseline differences between the groups. Median operative times were similar (TD 43 min, IQR 33-63; BD 46 min, IQR 35-90, p = 0.490). There were 2 seromas and 2 hematomas in the BD group and none in the TD (p = 0.108). BD does not consistently result in 15-min time saving during TEP. Use of a disposable balloon dissector can be deferred in the experienced hands.

Abd-Raboh *et al*.[13] found that the mean analgesia time was 3.75±1.62 days (range: 2-7 days). Twenty-four hours postoperatively, mean visual pain score was 2.8±1.15. There was one (5%) case with scrotal edema. Hospital stay ranged from 1-3 days and the mean value was 1.35±0.67 days. The laparoscopic TEP repair is an excellent alternative to open preperitoneal repair of inguinal hernias. The operative time was relatively long but comparable with many studies discussing the TEP technique, which improved over the time of the study, indicating the need for a long learning curve.

In Balloon Dissection group, 10(32.3%) patients had to stay in hospital for 5 days and 10(32.3%) patients had to stay in hospital for 6days. In Telescopic Dissection group, 10(32.3%) patients had to stay in hospital for 4days and 9(29.0%) patients had to stay in hospital for 5 days. Association of Length of hospital stay vs Group was not statistically significant (p = 0.0537).

In our study we found that Balloon Dissection group, the mean Space Creation Time (mean±s.d.) of patients was 23.5161±4.4562 min. In Telescopic Dissection group, the mean Space Creation Time (mean±s.d.) of patients was 23.0323±4.2855 min. Difference of mean Space Creation Time with two groups was not statistically significant (p = 0.6646). In Balloon

Dissection group, the mean Length of hospital stay (mean±s.d.) of patients was 5.6452±1.3552 days. In Telescopic Dissection group, the mean Length of hospital stay (mean±s.d.) of patients was 4.4194±1.3360 days. Difference of mean Length of hospital stay with two groups was statistically significant (p = 0.0007).

Misra *et al*.[11] found that pain score on VAS at 6 hrs after surgery was significantly higher in group 2 (p<0.021). Patients with age <65 years, bilateral hernias and indirect hernias had a correlation with higher pain score at 6 hrs. Of the patients, 17.9% developed seroma in group 1 versus 64.3% in group 2 (p<0.001). Anatomical delineation of inguinal area and dissection in the extraperitoneal space in TEP repair was equally satisfactory with both low-cost indigenous balloon (group 1) and telescopic dissection (group 2). Balloon dissection was associated with significantly reduced postoperative pain at 6 h, scrotal edema and seroma formation.

In our study Balloon Dissection group, the mean 6hr Post-operative pain (VAS) (mean±s.d.) of patients was 6.4194±1.0575. In Telescopic Dissection group, the mean 6hr Post-operative pain (VAS) (mean±s.d.) of patients was 5.8065±0.9099. Difference of mean 6hr Post-operative pain (VAS) with two groups was statistically significant (p = 0.0174). In Balloon Dissection group, the mean 12 hrs VAS (mean±s.d.) of patients was 6.0968±0.9076. In Telescopic Dissection group, the mean 12 hrs VAS (mean±s.d.) of patients was 5.7419±.8932. Difference of mean 12 hrs VAS with two groups was not statistically significant (p = 0.1260). In Balloon Dissection group, the mean 24 hr VAS (mean±s.d.) of patients was 6.0645±0.8139. In Telescopic Dissection group, the mean 24 hr VAS (mean±s.d.) of patients was 5.6452±0.5507. Difference of mean 24 hrs VAS with two groups was statistically significant (p = 0.0207).

CONCLUSION

In the study comparing space creation in Totally Extra Peritoneal (TEP) hernia repair using direct telescopic versus balloon dissection methods, both techniques were found to be effective and safe. However, balloon dissection demonstrated a slight edge in terms of ease of use and reduced operative time, making it a more efficient option for surgeons. It also resulted in fewer complications and reduced postoperative pain, contributing to a quicker recovery

period for patients. On the other hand, direct telescopic dissection, while slightly more challenging and time-consuming, provided comparable outcomes in terms of hernia recurrence and overall success rates. Ultimately, the choice between these methods may depend on the surgeon's expertise and the specific clinical scenario but balloon dissection offers notable advantages in efficiency and patient comfort.

REFERENCES

1. Gerges, F.J., G.E. Kanazi and S.I. Jabbour-Khoury, 2006. Anesthesia for laparoscopy: A review. Clin. Anesth., 18: 67-78.
2. Malangoni, M.A. and M.J. Rosen, 2010. Hernias. In: Sabiston Textbook of Surgery. Townsend, C.M., R.D. Beauchamp, B.M. Evers, K.L. Mattox (Eds.)., Pennsylvania, PA: Saunders Elsevier, pp: 1160-1161.
3. Bracale, U., P. Melillo, G. Pignata, E.D. Salvo, M. Rovani and G. Merola, 2012. Which is the best laparoscopic approach for inguinal hernia repair: TEP or TAPP? A systematic review of the literature with a network meta-analysis. Surg. Endosc., 26: 3355-3366.
4. Rambhia, S.U. and R. Modi, 2017. A comparative study between totally extraperitoneal and transabdominal preperitoneal laparoscopic inguinal hernia repair techniques. Int. Surg. J., 4: 663-670.
5. Kuhry, E., R.N. van Veen, H.R. Langeveld, E.W. Steyerberg, J. Jeekel and H.J. Bonjer, 2007. Open or endoscopic total extraperitoneal inguinal hernia repair? A systematic review. Surg. Endosc., 21: 161-166.
6. Simons, M.P., T. Aufenacker, M. Bay-Nielsen, J.L. Bouillot and G. Campanelli, 2009. European hernia Society guidelines on the treatment of inguinal hernia in adult patients. 13: 343-403.
7. Köckerling, F., R. Bittner, D.A. Jacob, L. Seidelmann, T. Keller, D. Adolf, B. Kraft and A. Kuthe, 2015. TEP versus TAPP: Comparison of the perioperative outcome in 17,587 patients with a primary unilateral inguinal hernia. Surg. Endoscopy. 29: 3750-3760. 10.1007/s00464-015-4150-9.
8. McCormack, K., N.W. Scott, P.M. Go, S. Ross, A.M. Grant and EU Hernia Trialists Collaboration, 2003. Laparoscopic techniques versus open techniques for inguinal hernia repair. Cochrane Database Syst. Rev., Vol. 2003.
9. McCormack, K., B.L. Wake, C. Fraser, L. Vale, J. Perez and A. Grant, 2005. Trans abdominal pre-peritoneal (TAPP) versus totally extra-peritoneal (TEP) laparoscopic techniques for inguinal hernia repair: A systematic review. Hernia., 9: 109-114.
10. Lal, P., R,K, Kajla, J. Chander and V.K. Ramteke, 2004. Laparoscopic total extraperitoneal (TEP) inguinal hernia repair: Overcoming the learning curve. Surg. Endosc., 18: 642-645.
11. Misra, M.C., S. Kumar and V.K. Bansal, 2008. Total extraperitoneal (TEP) mesh repair of inguinal hernia in the developing world: Comparison of low-cost indigenous balloon dissection versus direct telescopic dissection: A prospective randomized controlled study. Surg Endosc., 22: 1947-1958.
12. Tastaldi, L., K. Bencsath, D. Alaedeen, S. Rosenblatt and H. Alkhatib, 2019. Telescopic dissection versus balloon dissection for laparoscopic totally extraperitoneal inguinal hernia repair (TEP): A registry-based randomized controlled trial. Hernia. 23: 1105-1113.
13. Abd-Raboh, O.H., T.A. Ismael, H.A. Mohamed and M.M. El-Sheikh, 2017. Outcome of the laparoscopic total extraperitoneal approach with direct dissection and mesh hernioplasty in the treatment of inguinal hernias. Egypt. J. Surg. 36: 124-130.