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EVALUATION OF SAFETY AND COMPLICATIONS OF THE LAPAROSCOPIC TOTAL EXTRA PERITONEAL PROCEDURE (LAP TEP) VERSUS LICHTENSTEIN'S REPAIR FOR INGUINAL HERNIA

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ABSTRACT: OBJECTIVES: To evaluate the safety and complications of the Laparoscopic Total Extra Peritoneal Procedure (LAP TEP) versus Lichtenstein's repair for Inguinal Hernia. Design: Prospective comparative study of 70 patients in the age group 18-80yrs with inguinal hernia. Setting: department of surgery, NKPSIMS & R.C. & Lata Mangeshkar Hospital, Hingna, Digdoh Hills, Nagpur from April 2012 to March 2014. Result: Mean age of patients in laparoscopy TEP repair were 49.40 ± 17.88 & in open were 49.85 ± 16.05 (p value 0.638). The mean time of surgery was higher in the laparoscopic group (1.42 ± 0.015) as compared to the open group (0.49 ± 0.01), this is due to the learning curve. A significant percentage of patients in the open group had fever due to wound infection this could be explained by the fact that most of the cases in the open group were done by residents. A higher incidence of cord edema was seen in the laparoscopic group (52%) as compared to the open group (11%), this may be due to the increased cord handling during the procedure. A higher incidence of haematoma was also seen in the laparoscopic group (20%) this again may be due to the learning curve and increased handling in the initial cases. Conclusion: laparoscopic hernia repair though being superior in terms of less pain and early return to active work is more expensive and requires specialised training. Laparoscopy is not a gold standard but in selected cases and in the hands of expert it is an excellent procedure.

KEYWORDS: inguinal hernia, LAP TEP, Lichtenstein's repair.

INTRODUCTION: Hernia is as ancient as man himself. Sir Percivall Pott in 1756 stated about hernia that "it is the disease that makes the subject of the following tract, is one in which mankind are on many accounts, much interested. It sometimes puts the life of the patient in such hazard, as to require one of the most delicate operations in surgery, and it has in all the times, from the most ancient down to the present, rendered those who labour under it subject to the most iniquitous frauds and impositions."⁽¹⁾

Very few enthusiasts accept innovations in surgery without a critical evaluation. Most surgeons instinctively reject a new procedure, sometimes even after the procedure is validated by the initial phase of outcome data collection. The history of inguinal hernia repair over several decades amply illustrates how innovations are adopted into surgical practice through a combination of scientific and subjective processes. Each improvement goes through an initial process of emotional advocacy and knee-jerk rejection before being subjected to a critical outcome analysis⁽²⁾.

Inguinal hernia repair has been the traditional training ground for surgeons and is essential for honing technical skills as it is one of the commonest general surgical procedures performed.

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Unlike its open counterpart, Total Extra peritoneal Repair (TEP) is an advanced laparoscopic procedure. It requires greater skills of laparoscopic dissection and manipulation, as the working space available is limited. It has a considerable learning curve and must therefore be attempted only after acquiring adequate experience of basic laparoscopic procedures such as laparoscopic cholecystectomy, appendectomy, diagnostic laparoscopy, etc.⁽²⁾

If an open hernia repair seems preferable to a surgeon then the skill required for endoscopic hernia repair would be lost and, without that skill, the will to learn and achieve technical endoscopic excellence to apply to other intra-abdominal conditions will diminish. Laparoscopic inguinal hernia repair has been tested in number of trials but with conflicting results. However most of the trials are from western world, which does not reflect the true picture from developing countries. Hence the present study was design to evaluate the safety and complications of the Laparoscopic Total Extra Peritoneal Procedure (LAP TEP) versus Lichtenstein's repair of Inguinal Hernia.

MATERIALS AND METHODS: This was a prospective study was carried out in 70 patient in the department of surgery, NKPSIMS &R.C. & Lata Mangeshkar Hospital, Hingna, Digdoh Hills, Nagpur from April 2012 to March 2014.

INCLUSION CRITERIA:

- Reducible inguinal hernia
 - All inguinal hernia between 18-80 yrs of age.
- Exclusion criteria:
- Very large hernia
 - All complicated hernia i.e. strangulation, obstruction & irreducible.
 - Paediatric hernias.
 - Unfit cases for general anaesthesia
 - Patient with previous lower abdominal scar

A thorough history was taken of the presenting illness and co-morbid conditions, if any. In patients with hypertension and coronary artery disease, a special note is to be made regarding intake of anti-coagulants. Besides the routine blood and urine investigations, a coagulation profile was performed, as an intractable coagulopathy is an absolute Contraindication for endoscopic surgery.

Preoperative preparation

The patient had explained the various available modalities of treatment with their potential benefits, material risks and the possibility of conversion to open surgery if there are technical difficulties or in the interest of the patient's safety and well-being. Patients were selected randomly and written, informed, valid consent obtained from all the patients.

LAPAROSCOPIC TOTAL EXTRAPERITONEAL REPAIR: The core equipment required for laparoscopic procedures is the endovision system, which consists of the telescope 0 and 30 degree, endovision camera, light source, fibreoptic cable and video monitor.

Other electronic equipment required is:

- 1) CO₂ insufflator
- 2) Suction

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- 3) Irrigation system
- 4) Energy sources(cautery)
- 5) Archival/recording units

MECHANICAL INSTRUMENTS: Blunt trocar (10 mm) was required for open access to the extraperitoneal space and was used for introduction of the telescope.

Two 5 mm trocars for hand instruments. In case a 10 mm mesh-fixing device is used, an additional 10 mm trocar would be required.

EXTRA PERITONEAL ACCESS: An Infraumbilical, transverse, 12 mm incision is made on one side opposite to the side of the hernia. The anterior rectus sheath is exposed using blunt dissection. A transverse incision is then made on the anterior rectus sheath to one side of the midline to avoid inadvertent opening of the peritoneum. Using finger dissection, a space is created between the rectus muscle on the same side.

PORT PLACEMENT: A 10 mm port with blunt trocar (blunt tip) is introduced into the preperitoneal tunnel through the infra umbilical incision and is secured with stay sutures. To avoid excessive subcutaneous emphysema, we kept the pressure below 12 mmHg.

A 10 mm 30° telescope mounted on the camera head is introduced through the infra umbilical port. Blunt dissection with the telescope is done in the midline to clear the area of all loose areolar tissue for the introduction of accessory ports. The port was anchored to the skin with sutures to avoid getting displaced. Next two working ports are placed in the Pre peritoneal space, first 5 mm port is placed approximately 2 cm above the pubis in the midline and second 5/10 mm port is placed midway between the two placed ports (subumbilical and suprapubic) in the midline.

OPEN METHOD: The Lichtenstein Tension Free Repair was done with a sheet of polypropylene mesh measuring approximately 8 X 6 cm is trimmed to fit the area exposed and used to reconstruct the entire floor of the inguinal canal without any attempt to close the defect by suture. The mesh is sutured along its lower edge to the pubic tubercle, the lacunar ligament, and the inguinal ligament to beyond the internal ring with a continuous suture of the monofilament 3-0 polypropylene. The medial edge is sutured to the rectus sheath, also with a continuous suture of 3-0 polypropylene.

The superior edge is tacked down to the aponeurosis or the muscle of the internal oblique with a few interrupted sutures. The lateral edge of the mesh is slit and the two tails passed around to embrace the cord at the internal ring; they then are crossed over each other and tacked down to the inguinal ligament with one polypropylene suture. This creates a new internal ring and the shutter mechanism. The external oblique aponeurosis then is re-sutured in-front of the cord. This is completely tensionless repair and requires no formal reconstruction of the canal floor.

OBSERVATIONS: The comparative prospective study was conducted on 70 patients, 25 patients under went laparoscopic TEP and 45 open lichtenstein repair. The demographic profile of the patients given in the following tables

AGE INCIDENCE: Majority of the cases in the laparoscopic group belongs to the 5th decade and open group belonged to 7th decade.

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SR. No.	AGE(IN YEARS)	LAP CASES(%AGE)	OPEN CASES(%AGE)
1	20-30	3(12%)	7(14.89%)
2	31-40	3(12%)	9(20%)
3	41-50	9(36%)	8(17.77%)
4	51-60	3(12%)	7(14.89%)
5	61-70	2(8%)	12(25.53%)
6	71-80	4(16%)	3(6.38%)
TABLE 1			

GENDER DISTRIBUTION: In our study only one female patient with inguinal hernia was encountered.

Side distribution: right side was more common in both the groups.

SR. NO.	SIDE	LAP CASES (%AGE)	OPEN CASES (%AGE)
1	Right Side	19(76%)	25(55.55%)
2	Left Side	5(20%)	15(33.33%)
3	B/L	2(8%)	5(11.11%)
Table 2			

TYPE OF HERNIA: In both groups indirect inguinal hernia was more common

SR. NO.	TYPE	LAP CASES (%)	OPEN CASES (%)
1	INDIRECT	23(92%)	39(86.6%)
2	DIRECT	2(8%)	6(13.33%)
TABLE 3			

Operating time: maximum time required for open cases was 1 hr and in laparoscopic cases it was 2 hrs.

SR.NO.	TIME IN HRS	LAP CASES (%)	OPEN CASES (%)
1	0-1 Hrs	1(4%)	41(91.11%)
2	1-2 Hrs	19(76%)	4(8.88%)
3	2-3 Hrs	4(16%)	0
TABLE 4			

VISUAL ANALOGUE SCORE: Higher percentage of patients having a high V.A.S. on day zero, this rapidly decreased on day1 and day 2 in the laparoscopic group. By day 8, the V.A.S. was lower in the laparoscopic group than in open repair group.

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	Lap Cases	Open Cases	
	n=25	n=45	P Value
VISUAL ANALOGUE SCORE(DAY 0)	8.52+0.51	7.87+0.84	p=0.0008
VISUAL ANALOGUE SCORE(DAY 1)	6.32+0.804	3.52+1.08	p<0.0001
VISUAL ANALOGUE SCORE(DAY 2)	3.52+1.08	3.64+1.05	p=0.651
VISUAL ANALOGUE SCORE(DAY 3)	1.56+1.12	2.24+1.00	p=0.011
VISUAL ANALOGUE SCORE(DAY 8)	0.52+0.59	0.42+0.58	p=0.494
VISUAL ANALOGUE SCORE(Discharge)	0.16+0.37	0.07+0.25	p=0.23

Table 5

STATISTICAL SIGNIFICANCE OF MEAN AGE, GENDER, TIME OF SURGERY AND COMPLICATIONS:

Mean age of our patients in both group were similar. There was only one female in the open group who had a large hernia. The mean time of surgery was higher in the laparoscopic group (1.42 ± 0.015) as compared to the open group (0.49 ± 0.01), A higher incidence of cord oedema was seen in the laparoscopic group (52%) as compared to the open group (11%). A higher incidence of haematoma was also seen in the laparoscopic group (20%). A higher incidence of wound infection was seen in the open group (22.22%)

	Data for Lap Cases n =25	Data for Open Cases n =45	p Value
Age(years)	49.40 $\pm$ 17.88	49.85 $\pm$ 16.05	0.638
Sex(M/F)	25/0	44/1	1
Time of Surgery	1.42 $\pm$ 0.015	0.49 $\pm$ 0.01	p<0.0001
Fever	25(4) (16%)	45(6) (13.33%)	0.736
CORD OEDEMA	25(13) (52%)	45(5) (11.11%)	0.006
HAEMATOMA	25(5) (20%)	45(5) (11.11%)	0.485
WOUND INFECTION	25(4) (16%)	45(10) (22.22%)	0.764

Table: 6

OTHER COMPLICATIONS

PENILE OEDEMA	1(2.22%)	1(2.12%)	1
COLLECTION IN THE SCROTUM	6(13.33%)	0	0.003
INDURATION AT SURGICAL SITE	4(8.88%)	0	0.02
EARLY RECURRENCE	1(2.22%)	0	0.366

DISCUSSION: Majority of the cases in the laparoscopic group in our study belong to the 5th decade and in open group belonged to 7th decade. This however may be because we had a larger sample size in the open group. However our study does match with age incidence studies as done by Celestin ⁽³⁾

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and G L Jatkar ⁽⁴⁾. We encounter one female patient with inguinal hernia, representing 1.43% of our study sample. This is consistent with a higher incidence of inguinal hernias in male. The other studies showed a similar incidence.

Sr. no.	AUTHOR	MALE:FEMALE
1	Ian Aird ⁽⁵⁾	100:1
2	Celestin ⁽³⁾	10:1
3	Deshmane ⁽⁶⁾	100:1
4	Jack abrahmson ⁽⁷⁾	4:1
5	Gianetta et al ⁽⁸⁾	19.1:1

Right side indirect inguinal hernia was more common in both groups. This is consistent with world-wide higher incidence of hernia also shown in studies done by Palumbo & Shape⁽⁹⁾ and Jatkar series⁽⁴⁾ and MedIndia ⁽¹⁰⁾ 16 % of the cases took up to 3 hrs this could be because of the learning curve and it took some time for the operation theatre (O.T.) staff to get adjusted to the procedure however once the system became streamlined the remainders 19 (76%) were done within 2 hrs. Technology appraisal guidance 83.

Laparoscopic surgery for Inguinal Hernia repair, issued by National Institute for clinical Excellence, UK. Issue date September 2004 ⁽¹¹⁾, stated that laparoscopic surgery was associated with a statistically significant increase in operation time compared with open methods of hernia repair. Despite a higher percentage of patients having a high V.A.S. on day zero, this rapidly decreased on day 1 and day 2 in the laparoscopic group. By the day 8, the V.A.S. was lower in the laparoscopic group than in open repair group.

The higher initial score could be explained due to longer operative time and residual pneumoperitoneum however recovery was faster in the laparoscopic group due to smaller incisions. However study done by Sudhir Kumar Jain and Choden Norbu et al ⁽¹²⁾ found that Post-Operative pain was found to be less in laparoscopic hernia repair group across the board. VA group ⁽¹³⁾ did not find any difference in post-operative pain after 14 days.

Stoker et al ⁽¹⁴⁾ found less post-operative pain for the first 4 hours after open hernia repair probably due to effect of local anesthesia. There was only one female in the open group who had a large hernia, therefore open repair was done rather than TEP. The mean time of surgery was higher in the laparoscopic group (1.42 ± 0.015) as compared to the open group (0.49 ± 0.01), this is because the initial four cases took a longer time due to the learning curve.

The direct inguinal hernia cases in the laparoscopic group took a shorter time as less amount of dissection was required. A higher incidence of cord oedema was seen in the laparoscopic group (52%) as compared to the open group (11%), this may be due to the increased cord handling during the procedure. A higher incidence of haematoma was also seen in the laparoscopic group (20%) this again maybe due to the learning curve and increased handling in the initial cases. We also observed a cough impulse in one of the cases of haematoma which was initially thought to be a recurrence but subsequently subsided and were thought to be a transmitted impulse.

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A higher incidence of wound infection was seen in the open group but this could be explained by the fact that most of the cases in the open group were done by residents. One early recurrence was seen in the laparoscopic group and none in the open group. We did not encounter any major Vascular or neural injuries in the laparoscopic Group.

In an extensive review by Cochrane group ⁽¹⁵⁾ in conjunction with European Hernia trialist group, found serious vascular and visceral injuries more often in laparoscopic group (visceral injuries 8:2315 and vascular injuries 7:2498). Other studies done by Sabanci et al ⁽¹⁶⁾ showed complications like seroma (5.1%) and recurrence (10%).

Majority (80%) of the laparoscopic patients were discharged on the on the 3rd post-operative day. Whereas in the open group majority (62.22%) were discharged on the 8th post-operative day. There were delayed discharges in both groups on the 14th post-operative day which were mainly due to complications such as infection. However, ours being a rural referral hospital and patients coming from a distance they preferred being discharged after suture removal as it was not convenient to revisit. This could reflect the late discharges in the laparoscopic group.

CONCLUSION: Laparoscopic hernia repair though being superior in terms of less pain and early return to active work is more expensive and requires specialised training. However, if this procedure is not practised in teaching hospital the skill would be lost.

Our study has demonstrated similar findings, we do not advocate laparoscopy as gold standard but in selected cases and in the hands of expert it is an excellent procedure.

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