



Randomised Prospective Comparative Evaluation of Laparoscopic Orchidopexy versus Open in Children with Non Palpable Testis



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Abstract

Background: Cryptorchidism is one of the most common congenital anomalies, occurring in 1% to 4% of full-term and 1% to 45% of preterm male neonates. It can occur in isolation or as a part of a syndrome. The purpose of this study was to compare the outcome of laparoscopic and open orchidopexy at a single centre.

Material and Methods: This prospective comparative study was carried out in the postgraduate Department of General Surgery, Government Medical College, Srinagar from May 2010 to November 2012. 60 patients underwent orchidopexy during this period, open (n=30) and laparoscopic (n=30). We included all children up to the age of 16 years with unilateral or bilateral nonpalpable testes and excluded all children having any contraindication to either of the approaches in order to remove the selection bias. Moreover all the procedures were done by a single surgical team.

Results: Patients in both the groups were comparable in terms of mean age and laterality of disease. Out of 60 cases of undescended testes ultrasonography of the groin and abdomen could localize testis accurately in only 53 patients. Of the 7 missed testicles, 5 were found during initial diagnostic laparoscopy and the other two were found during open orchidopexy procedure. Thus the sensitivity of transcutaneous ultrasonography in localizing the undescended testis is 83.33% as against 100% in laparoscopy. Mean hospital stay was calculated in the two groups. The difference was statistically insignificant between the lap and open groups (1.3 vs 2.1 days; $p > 0.5$). Postoperative pain was quantified using the total number of doses of analgesic, diclofenac sodium, (i/m Inj or suppository) used in the postoperative period. There was a statistically significant difference in the quantity of diclofenac used in the two groups. Laparoscopic orchidopexy group had generally lesser use of analgesics.

There were ten postoperative complications in total; six in the laparoscopic group and four in the open group. The complications were relatively severe in the open group and added to hospital stay and morbidity significantly. The mean period of return to normal activity in open and laparoscopic groups was 1.5 and 1.1 weeks with p value > 0.05 . Laparoscopic surgery was significantly costly because of use of disposable trocars. However due to short hospital stay, lesser morbidity and shorter convalescence, overall costs associated are expected to be reduced.

Conclusion: Laparoscopy is a definite diagnostic modality in cases of non-palpable testis even if, other diagnostic modalities are unequivocal. Laparoscopy offers a great deal of advantage in cases of bilateral non-palpable testes as both pathologies can be addressed at the same time in a single sitting. Laparoscopy offers us advantage in high undescended testis as mobilization of cord can be done without any extensive dissection in contrast to open orchidopexy technique. In addition, laparoscopy provides significantly less morbidity, is less painful, has lesser hospital stay and is cosmetically better.

Keywords: Cryptorchidism; Laparoscopy

Introduction

Cryptorchidism is one of the most common congenital anomalies, occurring in 1% to 4% of full-term and 1% to 45% of preterm male neonates. It can occur in isolation or as a part of a syndrome [1,2]. The majority of cases are isolated, with the ratio of non-syndromic to syndromic cryptorchidism reported

as greater than 6: 1. An incidence of cryptorchidism of about 1% is reported by age 1 year and about 20% of children with cryptorchidism may have one or both non-palpable testes [3-5]. The condition of non-palpable testis may fall into one of the following categories: agenesis, vanishing testes, intra-abdominal testes or inguinal testes [6,7]. The etiology of cryptorchidism is

multifactorial but the exact mechanism of cryptorchidism has proven to be elusive. Birth weight is the principal determining factor for undescended testes at birth to age one year, independent of the length of gestation [8]. Testosterone and its conversion to dihydrotestosterone (DHT) are also necessary for continued migration, especially during the inguinoscrotal phase [9-11].

Correction of cryptorchidism is indicated to optimize testicular function, potentially reduce and/or facilitate diagnosis of testicular malignancy, provide cosmetic benefits, and prevent complications such as clinical hernia or torsion. In infants, observation is indicated for the first six postnatal months to allow spontaneous testicular descent. If descent does not occur in the postnatal period, present consensus supports surgical treatment. The recommended age for surgical intervention has gradually declined over the years and current recommendation is age of 6 months in full term males in whom the testes have failed to descend. Although various imaging modalities i.e. ultrasonography, CT and MRI have been used to locate non-palpable testes in boys, none has been able to provide comparable accuracy to laparoscopy [3,12]. The finding of bilateral non-palpable testes however represents a special situation that may warrant further investigations to rule out inter-sex abnormalities which may have life threatening implications in the neonatal period, especially associated with severe hypospadias.

Although numerous strategies exist for the treatment of boys with non-palpable testes, controversy remains concerning the most effective treatment. Traditionally, an open inguinal exploration was undertaken to locate the missing testis, followed by a conventional orchidopexy. With the advancements in laparoscopic techniques and instruments, laparoscopy has been established as the most reliable diagnostic and therapeutic modality for the management of non-palpable testis. It clearly demonstrates the anatomy and provides visual information upon which a definitive decision can be made. Laparoscopic orchidopexy has begun to surpass surgical exploration as the primary treatment in boys with non-palpable testis, gaining wide acceptance in the surgery community as the most effective means of relocating an intra-abdominal testes to a dependent position.

Aims and Objectives

This randomized comparative prospective study was carried out with the aim to compare the outcome of laparoscopic and open orchidopexy at a single centre in terms of:

- i. Sensitivity and specificity in localizing non-palpable testis
- ii. Mean operative time.
- iii. Conversion rate and reasons thereof.
- iv. Complications
- v. Intraoperative

- vi. Postoperative
- vii. Mean visual analogue score and analgesic requirements.
- viii. Mean postoperative hospital stay.
- ix. Mean time taken for return to activities of daily life.

Materials and Methods

This prospective comparative study was carried out in the postgraduate Department of General Surgery, Government Medical College, Srinagar from May 2010 to November 2012. All patients who presented to the outpatient department with complaints of absent testes were examined and those with non-palpable testes were included in the study. They were randomly divided using a computer based number randomization program in two groups, laparoscopic & open group respectively. 60 patients underwent orchidopexy during this period, open (n=30) and laparoscopic (n=30), after evaluating them for inclusion and exclusion criteria. Laparoscopic group patients with non-palpable testes were subjected to diagnostic and operative laparoscopy.

In our study, we included all children up to the age of 16 years with unilateral or bilateral nonpalpable testes and excluded all children having any contraindication to either of the approaches in order to remove the selection bias. Moreover all the procedures were done by a single surgical team. Preoperative assessment of patients was done. Intraoperatively note was made of following parameters.

- i. Operative time.
- ii. Intraoperative complications.
- iii. Conversion to open with reasons.

Post operative assessment of patients included hospital stay and post operative requirements for analgesia. Patients undergoing surgery were followed for 6 months (weekly for first month, at 6 weeks, at 6 months) and return to routine work.

Laparoscopic Orchidopexy

A day before the surgery soft diet was started with 4-6 hours of preoperative fasting as required according to the age of the patient on the day of surgery. Older children were asked to empty the bladder and injection ceftriaxone 15-20mg/kg was given at the time of induction of anaesthesia in the operation theatre. The patients were placed in the supine position with both arms along the sides. Inguinal examination was performed in each child under anaesthesia to confirm the preoperative diagnosis. The procedure was done under general anaesthesia. Children were premedicated with syrup promethazine (Phenergan) 0.4mg/kg given 2 hours before shifting to operation theatre.

Using a number 11 scalpel, a 10mm stab incision was made in the superior rim of the umbilicus. Pneumoperitoneum was established (10mmHg) by closed technique with the patient in a

300 head down Trendelenburg position and the primary 10mm camera port is introduced followed by camera. The area of the internal inguinal ring was inspected bilaterally and subsequent trocars placed under laparoscopic visualization into the right and left lumbar region in line with the umbilical port. A diagnostic laparoscopy was done for rest of the abdominal quadrants in all cases. Inguinal ring was first examined to evaluate its patency, and then the iliac areas and pelvis were inspected. If intra-abdominal blind ending cord structures were found, no further exploration was performed and a diagnosis of intra-abdominal vanishing testes was made. If an intra-abdominal testis is found; it was classified as high and low depending on its position with respect to the internal ring; high i.e. testis in the iliac fossa or pelvic inlet or pelvis (>2cm from the internal ring) and low i.e. testis adjacent to the internal ring/emergent testis(<2cm from the internal ring). With gentle traction on the testis, the most distal gubernacular attachment was divided with electric hook cautery and gubernaculum forming a handle for mobilizing the testis.

Stretch maneuver can be performed to see the mobility of the testis. Dissection was started lateral to the spermatic vessels and continued in cephalic direction over the iliac vessels. Once the testis was adequately mobilized which was confirmed by performing stretch maneuver where the testes is stretched to the contralateral inguinal ring. The dissection was further carried out medially all around the ring to complete the herniotomy. Peritoneal coverage between the vas deferens and urinary bladder was dissected. A triangular area of peritoneum between vas deferens and testicular vessels was left intact to preserve blood supply of testis. The pathway to the ipsilateral hemiscrotum was created. Usually a neotunnel was created between the medial umbilical ligament and the inferior epigastric artery (Prentiss maneuver) to gain extra length for reaching the scrotum. A blunt tip of the laparoscopic dissector was passed over the pubic bone into the ipsilateral hemiscrotum thus creating a pathway.

A dartos pouch was prepared in the hemiscrotum. A suction cannula was passed along the passage which was created transabdominally by laparoscopic dissector and grasping the tip of the suction cannula a long curved clamp was passed into the abdominal cavity and stretched in all directions to create adequate passage for bringing the testes down. The testis was grasped, ensuring that only gubernacular tissue is grasped. The testis was brought out into the scrotum and the length checked by deflating the abdomen. Releasing the pneumoperitoneum gives additional length. Any tension found on the pedicle was released by further mobilization of the peritoneal flaps. Testes were fixed in scrotum using 5-0 chromic catgut suture. Testes with a long mesoorchium are found to have more mobility and were mobilized easily compared to testes which are attached to the retroperitoneum by narrow stalk or embedded in the retroperitoneum. At the end of the procedure, abdomen was examined for any bleeding, the pneumoperitoneum released,

trocars removed. Trocar sites were closed. Children were discharged home mostly after one day. All the patients were followed weekly for first month, at 6 weeks and at 6 months.

Open Orchidopexy

Preoperative preparation and type of anaesthesia was same as for the laparoscopic orchidopexy. The patient was positioned in supine position, part cleaned with povidone iodine 10% and draped. An inguinal crease incision was made and another incision was made in the scrotum. The testis was mobilized, brought down into scrotal sac and sutured in subdartos pouch. Data was collected and unpaired student's t-test was used to determine the significance of the difference between two independent groups among continuous variables. For Qualitative data Chi square test was used to see the significant difference in proportion between two groups. A p-value of < 0.05 was considered as significant. www.graphpad.com/quickcalcs website was used for evaluation of data.

Observations and Statistical Analysis

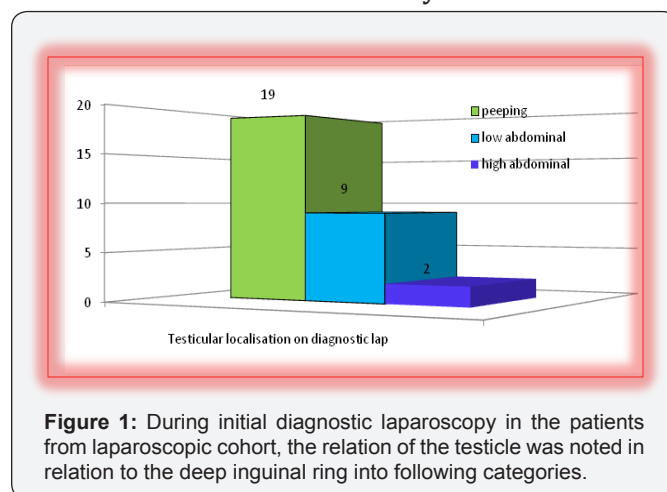


Figure 1: During initial diagnostic laparoscopy in the patients from laparoscopic cohort, the relation of the testicle was noted in relation to the deep inguinal ring into following categories.

The most common age group in both the laparoscopic as well as open orchidopexy cohorts was less than 5 years. The median age was 5.3 (range 1-17) and 5.7 years (range 1-16) in laparoscopic and open groups respectively and the youngest patient was of one year age in both the groups whereas the oldest was 16 and 17 years in both groups respectively. In the laparoscopic cohort 18 patients had right sided non-palpable testis, 10 had the left sided non-palpable testis and the rest 2 patients had bilateral abnormality. In the open cohort 15 had right sided undescended testis, 11 patients had left undescended testis and the rest 4 patients had bilateral abnormality. In open group bilateral cases were operated via the same modality with an interval of six weeks in between the intervention, but in laparoscopic group two patients with bilateral undescended were operated in single setting. Out of 60 cases of undescended testes ultrasonography of the groin and abdomen could localize testis accurately in only 53 patients. Of the 7 missed testicles, 5 were found during initial diagnostic laparoscopy and the other two were found during open orchidopexy procedure. Thus the sensitivity of transcutaneous ultrasonography in localizing the

undescended testis is 83.33% as against 100% in laparoscopy (Figure 1).

Peri-Operative details

Table 1: Comparison of operative parameters between open and laparoscopic Groups.

		Open Group	Laparoscopic Group	p-value
Operative Time (min)	Median	4 7	6 3	>0.05
	Range	30 - 85	41 - 97	
Blood Loss (ml)	Median	Minimal	Minimal	>0.05
Blood Transfusion(ml)		Nil	Nil	
Intra-Op Complications	Major	Nil 0%	Nil 0%	>0.05
	Minor	01 (3.33%)	02 (6.66%)	
Conversions		NA	Nil	
Oral Intake (hrs)	Mean	15.60	10.33	>0.05
	Range	12-30	8-24	

The location of the testicle, operative time, estimated blood loss, requirement for blood transfusions, intraoperative complications, conversion to open and reasons thereof were recorded. These parameters are depicted in Table 1.

Minor complications included port site bleed in one patient from the laparoscopic cohort which was managed conservatively by using laparoscopic monopolar diathermy; another patient from the same cohort had injury to the testicular artery which was then clipped using LT 300 titanium clips. All the laparoscopic procedures were completed successfully without the need for conversion. There was only one complication in the open cohort in the form of bleeding from pampiniform plexus which was managed with monopolarelectrocautery.

There were ten postoperative complications in total; six in the laparoscopic group and four in the open group. The complications were relatively severe in the open group and added to hospital stay and morbidity significantly.

Two patients in the open group developed superficial wound infection which was managed by a short course of empirical antibiotics against Staphylococcus aureus. Another patient developed hydrocele which regressed on conservative management. In the laparoscopic cohort, one patients developed surgical emphysema which was managed conservatively, another patient developed port site infection which needed daily dressings and the remaining two developed hydrocele which was again managed conservatively. Thus the complications which occurred in the open group were relatively severe and added to morbidity and hospital stay. The complications were statistically insignificant. On long term follow up a total of 3 patients developed atrophy of operated testicle; of these 2 were from the laparoscopic group. These complications are depicted in Table 2.

Table 2: Post-operative complications.

Complication	Open orchidopexy n=30	Laparoscopic orchidopexy n=30
n=30		
Sup. Wound infection	2	2
Hematoma / Collection	0	0
Fever	0	0
Prolonged Ileus	0	0
Pneumonia/ atelectasis	0	0
Subcutaneous emphysema	0	1
Hydrocele	1	2
Testicular atrophy	1	2
Recurrence	0	0
Total	4 (13.33%)	6(20%)

Table 3: Post operative pain -Analgesia requirement.

	Open group (n=30)	Lap. Group (n=30)	'p' value
Diclofenac(no. of doses)	2.3	1.2	>0.05
Inj + oral (mean)	(3-5)	(2-4)	

Most of the patients were discharged on first postoperative day. The longest hospital stay in the open group was for 5 days in the patient who developed severe superficial wound infection. The difference was statistically insignificant between the lap and open groups (1.3 vs. 2.1 days; p >0.5). Postoperative pain was quantified using the total number of doses of analgesic, diclofenac sodium, (i/m Inj or suppository) used in the postoperative period. There was a statistically significant difference in the quantity of diclofenac used in the two groups. Laparoscopic orchidopexy group had generally lesser use of analgesics Table 3.

Table 4: Follow up, recurrence and patient satisfaction.

	Open group (n=30)	Lap group (n=30)	'p' value
Follow up (months)			
Mean	8.3	7.5	>0.5
Range	4- 15	4-12	
Lost in follow up	-	-	

All patients in both groups were followed strictly after the surgery at regular intervals of 1 week for first month, at 6 weeks and at 6 months. There was significant difference in the satisfaction scores in the two groups. Parents of patients undergoing laparoscopic surgery were overall better satisfied. They were usually surprised by the results of the laparoscopic

surgery in the post operative period, with no incision and only three small dressings (band-aids) at the port sites. Moreover, laparoscopic orchidopexy was cosmetically better with an average scar size 1cm as against 3 cm of open orchidopexy. The results are shown in Table 4. The mean period of return to normal activity in open and laparoscopic groups was 1.5 and 1.1 weeks with p value > 0.05. Laparoscopic surgery was significantly costly because of use of disposable trocars. However due to short hospital stay, lesser morbidity and shorter convalescence, overall costs associated are expected to be reduced.

Discussion

Cryptorchidism is the most common abnormality of male sexual development. The testis can be ectopic, incompletely descended, retractile, and absent or atrophic [1,2]. Ultrasonography, CT scan and MRI are able to locate the testis in only 76% cases. Although numerous strategies exist for the treatment of boys with non palpable testes, controversy remains concerning the most effective treatment. Traditionally, an open inguinal exploration would have been undertaken to locate the missing testis, followed by a conventional or chidopexy or chidectomy [13,14]. Laparoscopy has been established as the most reliable diagnostic modality for the management of impalpable testis. Diagnostic Laparoscopy and Laparoscopic or chidopexy has begun to surpass surgical exploration as the primary treatment in boys with impalpable testes, gaining wide acceptance in the pediatric surgery community as the most effective means of relocating an intraabdominal testes to a dependent position [15-17].

The sample size of our study was 60 boys with 66 non-palpable testes. As our study was prospective and time limited, so the sample size was determined by these factors. Zubair Metal. [18] included 41 patients with 52 non-palpable testis in their study. Khan S et al. [19] Included 32 patients with 40 non-palpable testis in their study. In our study, patients of age group 1-17 years were included (1-16 in laparoscopic group and 1-17 in open group). The median age was 5.3 and 5.7 years respectively in lap and open groups which compares favourably with studies conducted by Satar N et al. [20] and Hvistendahl GM et al. [21]. 55% of our patients had right sided undescended testis whereas 35% patients in our study had left sided undescended testis. The remaining 10% (6 cases) had bilateral inflection. Ismail K et al. [22] reported 13.5% cases with bilateral undescended testis in their study whereas Hassan ME et al. [23] reported 21% cases with bilateral undescended testis. Trans-cutaneous USG for localization of non-palpable testis could localize testis in 83.33% patients in our study. In none of our patient CT or MRI was done.

Ismail K [22] in their study revealed that USG was helpful in localization of non-plapable testis in 100% of patients. This could be explained by the fact that colour Doppler study was utilized in that study. Khan S [19] in their study concluded that USG has ability to localize testis in 40% of patients. Closed technique of creating pneumoperitoneum was adopted in laparoscopic

patients. Diagnostic laparoscopy was done in all the patients. In our study laparoscopic determination of non-palpable testis was 100%. Bakr A [3] had laparoscopic yield of non-palpable testis of 95.3%. Zubair M [18] reported usefulness of laparoscopy in 80% of patients. Special mention of deep inguinal ring status was made. In our study, patients having closed deep ring was found in 28% patients and vas and vessels traversing it, was found in all of these patients which compares favorably with study conducted by Godbole PP et al. [24] and Masao T et al. [13] who reported 33% and 35% closed deep inguinal rings respectively. The significance of the fact lies in that these patients had testis in superficial inguinal pouch (ectopic testis).

Morphology of testis was noted in the laparoscopic group. Our study revealed normal testis in 54.5% of cases. Next common finding was hypo plastic testis (33.3%). Morphology of testis was correlated with localization of testis which revealed that features of hypoplasia were high in intra-abdominal testis. Similar findings were noted in study of Boekmann W [25] and Humphery GM [5]. The mean operative time in our study was 47 minutes (range 30-85) in open or chidopexy and 63 min (range 41-97 min) in laparoscopic cohort. Ahmad Abolyosr1 reported the operative time of 50.8 min and 65.6min in laparoscopic and open cohorts. This is in contrast to our study where open cases required lesser time than the laparoscopic ones. This may be explained by the initial learning curve phase of surgeons in our study. Argos MD [16] reported operating time of less than one hour in unilateral non-palpable testis and less than 2 hours in bilateral non-palpable testis. No major surgical complication was observed in either group.

The patients were on regular follow up. Postoperative testicular atrophy was seen in 3 patients with follow up till the study time; one from the open group and two from the laparoscopic group. The difference is though statistically insignificant. Ahmad abolyosr [1] documented five cases of testicular atrophy (three and two testes with open and laparoscopic second stage Fowler-Stephens orchiopexy, respectively) after 1 year of follow up. Khan S [19] et al. and Mehta KD et al. [17] reported no surgical complication in his study. This substantiates the fact, that complication rates are markedly reduced in good centres with high expertise.

The average postoperative hospital stay in our series was 2.1 days (range 1-5) for open orchidopexy and 1.3 days (range 1-2 days) for laparoscopic group. Koyama T reported hospital stay of less than one day in his patients. Time taken to return to daily activities was less in patients who underwent laparoscopic orchidopexy (1.1 weeks) as compared to patients who underwent open orchidopexy (1.5 weeks). As a diagnostic tool, laparoscopic yield of knowledge about non-palpable testis was 100%. Hinyokika N [7] found the effectiveness of laparoscopy with the advantage that one can visualize vessels and vas in addition to intra-abdominal testis. Godbole P [24] reported laparoscopy avoided negative exploration in 42% of non-palpable testis.

Conclusion

Laparoscopy is a definite diagnostic modality in cases of non-palpable testis even if, other diagnostic modalities are unequivocal. Laparoscopy offers a great deal of advantage in cases of bilateral non-palpable testes as both pathologies can be addressed at the same time in a single sitting. Laparoscopy offers us advantage in high undescended testis as mobilization of cord can be done without any extensive dissection in contrast to open or chidopexy technique. In addition, laparoscopy provides significantly less morbidity, is less painful, has lesser hospital stay and is cosmetically better.

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