Long-term outcome of laparoscopic & open Palomovaricocelectomy in terms of complications and recurrence rates

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Abstract

Objective: To investigate the long-term surgical outcome of open and laparoscopic Palomovaricocelectomy in terms of complications and recurrence rates over a 2-year period.

Methods: This is a retrospective comparative analysis of 72 patients who were operated for varicocele with openPalomo or laparoscopic ligation techniques between January 2014 and December 2015 at the department of Urological surgery, Hayatabad Medical Complex Peshawar Pakistan. Data was obtained prospectively about clinical features, treatment type, length of stay, complications occurrence and recurrence during the two-year period. Statistical analysis was done in order to compare the long-term outcome for the two procedures.

Results: 72 patients fulfilled the inclusion criteria with a mean follow up time of 16.25 months ± 4.99 SD. Out of these 42 (58.3%) were treated with the open technique while 30 (41.7%) with laparoscopic technique. Overall mean age was 23.82 years ± 4.86 SD with a mean duration of symptoms 11.06 months ± 5.59 SD. 72.4% of complications were encountered within the open Palomo technique group while 27.6% of complications occurred in the laparoscopic group. Similarly, 62.5% of the total recurrent cases occurred in the open group while 37.5% of recurrent cases occurred in the laparoscopic group. Median overall complications rate for open technique (mean rank = 40.00) and laparoscopic technique (mean rank = 31.60) were statistically significantly different, U = 483, z = -1.976, p = 0.048. The distribution of recurrence rates across the two treatment groups is also not significantly different, U = 618.00, z = -0.252, p = 0.801. On the other hand, the distribution of the varicocele grade was not statistically significantly different across the treatment groups, U = 582, z = -0.604, p = 0.546.

Conclusions: Laparoscopic and open Palomo techniques for varicocelectomy have comparable outcome in terms of recurrence rates. Overall incidence of complications is higher in the open group. Most of the complications resolve with conservative management.

Keywords: *Varicocele, laparoscopy, Palomo ligation, Outcome, Recurrence*

Introduction

Varicocele is one of the most commonly associated clinical disorder with male infertility. Its incidence is estimated at 4% to 25% of the young age male population, affecting up to 40% men with primary infertility and up to 70% with secondary infertility.[1] Clinically, varicocele is defined as abnormal dilatation of the veins of pampiniform plexus with reversal or reflux of blood flow.[2]

Although some experts on male infertility have questioned the benefits of varicocele surgery, others[3] have shown that varicocele repair does indeed improve non-obstructive azoospermia with a spontaneous pregnancy rate after varicocelectomy of up to 44.75%.[4, 5] Such high rates of attaining spontaneous pregnancies in previously infertile couples indicates that a varicocele should be operated in order to improve the male factor in an infertile couple.[6]

A multitude of treatment modalities have been introduced over the last two decades ranging from open ligation of the venous plexus to laparoscopic, percutaneous embolization and microsurgical techniques.[7, 8, 9, 10] All these surgical and interventional techniques have been shown to have benefits in one or many aspects.[11] The search for increasingly meticulous procedures has been stimulated by various factors, such as postoperative complications, recurrence in long-term or

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failure of the procedure to improve infertility or preoperative physical symptoms.[12, 13]

Laparoscopic advancements have led to adaptation of this modality for surgical treatment of varicocele with minimal invasiveness and improved postoperative complications as compared to the conventional open procedure.[14] However, there are studies[15, 16] which shows that despite quicker recovery times, less postoperative pain and safety in terms of postoperative complications, the laparoscopic technique does not differ from the open technique in terms of complications and recurrence.[8] Problems with open technique are recurrence, wound infection, postop pain, nerve injuries and hydrocele formation while with laparoscopic technique, hydrocele formation, recurrence and testicular artery injury with atrophy.[17]

We therefore, undertake this study in order to analyse the postoperative outcome of our patients in terms of length of stay, complication and recurrence rates in long-term for the laparoscopic and conventional open Palomo technique. This study will therefore try to highlight the features which could lead to identification of the effective procedure in terms of reduced complications and recurrence. Ultimately this will help improve outcome of our patients.

Methodology

Design: It was a retrospective cross sectional comparative study comparing two procedures for varicocele, done in last two years.

Setting: This study was conducted at the department of Urological surgery, Hayatabad Medical Complex, Peshawar. Approval of the institutes research & ethics committee was obtained before conducting the study.

Sampling Technique: Non probabilistic convenience sampling

Data Collection: This is a retrospective analysis of prospectively collected data of patients operated for varicocele between January 2014 and December 2015 with either of the two procedures, i.e., openPalomo or laparoscopic ligation procedures. Follow-up data ranged from 6 months to 24 months postoperatively. Preoperative clinical features such as age, duration of symptoms, pain, swelling and infertility, varicocele grade according to Dubin classification[18], laterality, procedure time and length of stay until discharge. Follow-up data included data about complications, such as wound infection, hydrocele formation, scrotal or wound haematoma formation, testicular atrophy, epididymitis, neurovascular injuries and recurrence of the varicocele during the follow-up period.

Inclusion Criteria
Patients of all ages with primary varicocele who were operated with laparoscopic or open procedure were included in the study.

Exclusion Criteria
Patients with varicocele due to malignancies and those with recurrent varicocele were excluded. Also we normally exclude patient from laparoscopic group who are operated for other procedures in the pelvic region.

Operative Procedure
All procedures were performed under GA. Perioperative intravenous antibiotics were given.

In the open Palomo high ligation technique, a grid-iron incision is used. The external oblique is incised along the line of fibres. The spermatic veins are approached extraperitoneally and divided between ligatures taking care of the internal spermatic artery and genitofemoral nerve branch. Closure is done in layers and scrotal support is given to all patients for at least 5 days.

In the laparoscopic technique, after inducing pneumoperitoneum with a Veress needle, the 3-port technique are employed. One 5 mm port at umbilicus is used for insertion of the telescope while a 10 mm port inserted in the right iliac fossa and another 5 mm port in the left iliac fossa. Careful dissection and identification of the gonadal vessels is done. The spermatic artery is saved while the veins are ligated with Liga-clips and then divided.

Postoperatively, two doses of intravenous antibiotics were given during the patient admission and dual intravenous analgesia was administered during the first 24 hours.

Follow-up
At discharge scrotal support was strictly advised and oral analgesics were prescribed on as need basis. Follow-up data was collected about complications, and recurrence. Appropriate treatment was provided in case of complications.

Data Analysis
The data was analysed using IBM SPSS Statistics (version 22.0). Descriptive statistics are mean ± standard deviations for continuous variables while frequencies and percentages are calculated for categorical variables.

Normality of the data was analysed using the Shapiro-Wilk test. Mean difference between the two treatment arms were analysed using the independent t-test while association for categorical dichotomous variables was determined with Chi-square tests. Spearman rank correlation test was performed for establishing correlation between various clinical variables to the outcome variables. In case of those variables where the continuous or ordinal data was not normally distributed, a Mann-Whitney U test was performed. A p-value of ≤0.05 was considered significant.

Results

72 patients fulfilled the inclusion criteria with an overall mean follow-up of 16.25 months ± 4.99 SD. Out of these 42 (58.3%) were treated with the open technique while 30 (41.7%) with laparoscopic technique. Overall mean age was 23.82 years ± 4.86 SD with a mean duration of symptoms 11.06 months ± 5.59 SD. Similarly, overall mean procedure time was 63.64 minutes ± 20.03 SD and an overall LOS of 3.22 days ± 0.92 SD. The treatment type and specific clinical features and outcome parameters are presented in

Table *1*&Table 2.

Table 1*:* Procedure specific distribution of clinical features

	Open technique (n = 42)		**Laparoscopic technique** (n = 30)	
Age (years)	22.43 ± 5.28		25.77 ± 3.42	
Sympt. Duration (months)	11.64 ± 6.19		10.23 ± 4.59	
Procedure time (minutes)	49.57 ± 9.80		83.33 ± 12.58	
LOS (days)	3.57 ± 0.94		2.73 ± 0.64	
Follow up (months)	15.52 ± 5.57		17.27 ± 3.92	
	freq.	**percent**	**freq**.	**percent**
Pain	27	64.3%	16	53.3%
Swelling	27	64.3%	15	50.0%
Infertility	22	52.4%	19	63.3%
Laterality				
Right	5	11.9%	4	13.3%
Left	34	81.0%	24	80.0%
Bilateral	3	7.1%	2	6.7%
Grade				
I	9	21.4%	5	16.7%
II	12	28.6%	8	26.7%
III	21	50.0%	17	56.7%

Complications	21	50%	8	26.7%

In a cross-tabulation analysis, 72.4% of complications were encountered within the open Palomo technique group while 27.6% of complications occurred in the laparoscopic group. Similarly, 62.5% of the total recurrent cases occurred in the open group while 37.5% of recurrent cases occurred in the laparoscopic group.A chi-square test for association was conducted between treatment type and overall incidence of complications. There was a statistically significant association between treatment type and overall incidence of postoperative complications, $\chi2(1) = 3.961$, $p = .047$. We also obtained statistically significant association between the open Palomo technique and the occurrence of postoperative scrotal haematoma, $\chi2(1) = 3.838$, $p = 0.05$. The association was moderately strong between operative technique and the overall incidence of complications, $\varphi = 0.235$, $p = 0.047$. However, an association of operative technique with the incidence of recurrence was not found to be associated with a particular procedure on Chi-square analysis, $\chi2(1) = 0.64$, $p = 0.80$.**Table 2**

Table 2: Procedure specific complications and recurrence rates

	Open technique (n = 42)		**Laparoscopic technique** (n = 30)		**χ2 sig.** (p)
Complications	freq.	percent	freq.	percent	0.048
Wound infection	4	9.5%	2	6.7%	0.665
Hydrocele	6	14.3%	4	13.3%	0.908
Testicular atrophy	-	-	1	3.3%	0.233
Epididymitis	3	7.1%	-	-	0.135
Scrotal hematoma	5	11.9%	-	-	0.050
Nerve injury	2	4.8%	-	-	0.225
Recurrence	5	11.9%	3	10.3%	0.800

A Mann-Whitney U test was run to determine if there were differences in overall and specific complications rates between open and laparoscopic procedures. Distributions of the complication rates for these two procedures were not similar, as assessed by visual inspection. Median overall complications rate for opentechnique (mean rank = 40.00) and laparoscopic technique (mean rank = 31.60) were statistically significantly different, $U = 483$, $z = -1.976$, $p = 0.048$. The distribution of recurrence rates across the two treatment

groups is also not significantly different, U = 618.00, z = -0.252, p = 0.801. On the other hand, the distribution of the varicocele grade was not statistically significantly different across the treatment groups, U = 582, z = -0.604, p = 0.546. The results of Mann-Whitney U test for specific complications distribution is shown in

Table *3*.

Table 3:Multiple Mann-Whitney U test results for categorical variables, group for the procedures

	Varicocele Grade	Neurovascular injury	Scrotal haematoma	Epididymitis	Testicular atrophy	Hydrocele	Wound infection	Overall Complications	Recurrence
Mann-Whitney U	582.000	600.000	555.000	585.000	609.000	624.000	612.000	483.000	618.000
Z	-0.604	-1.204	-1.945	-1.485	-1.183	-.114	-.429	-1.976	-.252
Asymp. Sig. (2-tailed)	0.546	0.229	0.052	0.138	0.237	0.909	0.668	0.048	0.801

An independent-samples t-test was run to determine if there were differences in procedure time between open and laparoscopic technique. The procedure time was lengthy for laparoscopic group (83.33 ± 12.58) than open technique (49.57 ± 9.80), a statistically significant difference of -33.762 (95% CI, -39.280 to -28.244), *t*(52.608) = -12.275, *p* = <0.001.**Table 4** The results of the independent samples t-test are shown in **Table 4**for other continuous variables with indication of the mean difference and appropriate confidence intervals. Also

Figure 1&

Figure 2

Table 4: Independent t-test for two treatment groups (continuous variables)

	t-test for Equality of Means						
						95% Confidence Interval of the Difference	
	t *	Df **	Sig. (2-tailed) ***	Mean Difference	Std. Error Difference	Lower	Upper

Patient age	Equal variances not assumed	-3.251	69.436	.002	-3.338	1.027	-5.387	-1.290
Symptoms duration	Equal variances not assumed	1.108	69.884	.272	1.410	1.272	-1.127	3.946
Procedure time	Equal variances not assumed	-12.275	52.608	.000	-33.762	2.750	-39.280	-28.244
Length of stay	Equal variances not assumed	4.498	69.869	.000	.838	.186	.466	1.210

- * = t, value of test statistics
- ** = Df, Degrees of freedom
- *** = Statistical significance

Figure 1: Mean procedure time for the two techniques

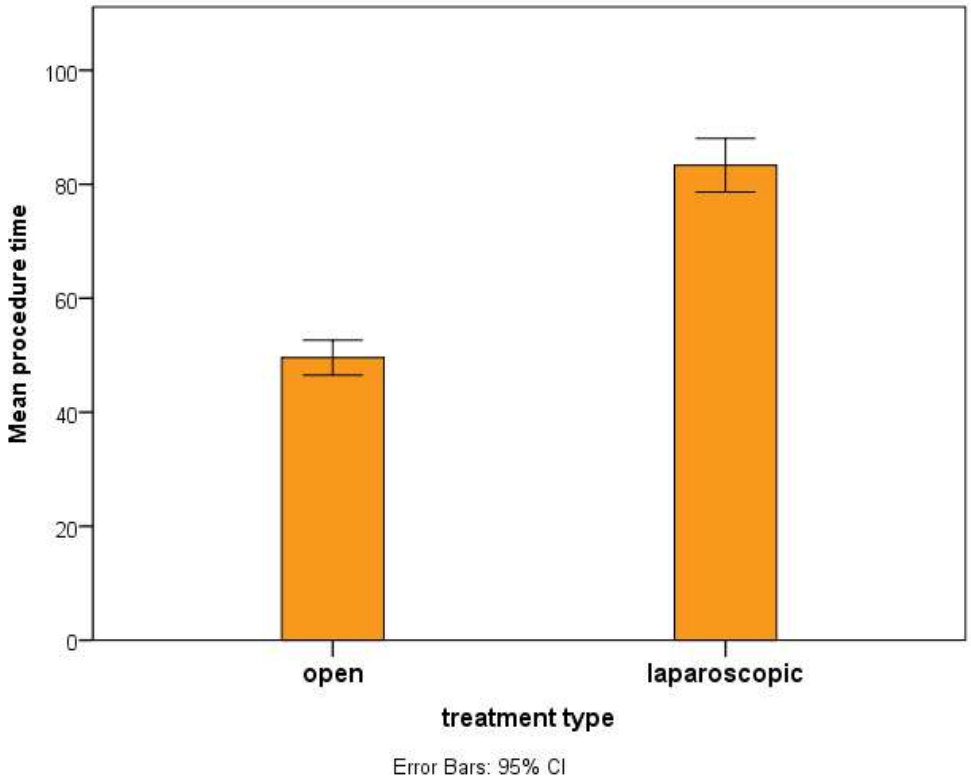
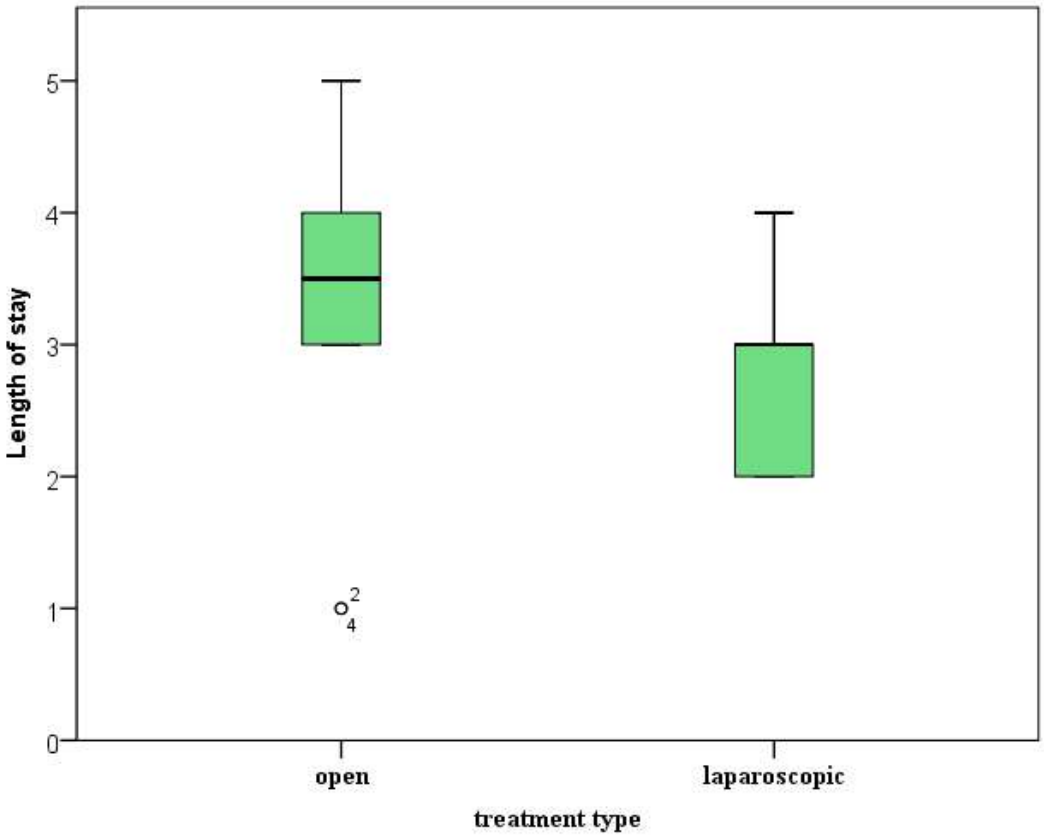


Figure 2: Mean length of stay (LOS) for the two techniques



Discussion

Varicocele has been shown to affect quality of life and fertility of young age male population, especially of the adolescents and young adults.[19] On top of this, various surgical techniques also bear morbidity which can lead to significant mental and physical suffering as well as financial costs.[20] Due to these reasons and with a significantly higher prevalence rate, it is imperative that surgical procedures be regularly evaluated for their associated postoperative morbidity and failure rates in terms of complications and recurrence. Postoperative complications in varicocele patients are of particular interest as these complications can either lead to the need of additional procedures such as hydrocelectomy or evacuation of scrotal haematoma.

Table *1* These demographic and clinical features are in agreement with most other studies and shows the significance of prevalence among young age male population and adolescents as well as nearly 60% of them seeking attention regarding treatment for infertility.[23, 24]Gorelick JL et al[1] has shown that on clinical examination a varicocele can be found in 35% of patients while 81% of secondary infertile men can have a varicocele.[1]

The open high ligation introduced by Palomo[21] in 1949 and the laparoscopic ligation are the two most commonly practiced surgical procedures in our country due to easy availability of equipment and patient affordability. Various clinical studies and meta-analysis have described the effectiveness of varicocele surgery in male factor infertility.[12, 22] Over the last two decades the laparoscopic approach has been favoured due to the less invasiveness of the procedure, shorter hospital stay, early return to work, fewer complications as well as its effectiveness in achieving a fairly acceptable recurrence rate.[8]

In our study we encountered fairly young age male patients (mean age = 23.82 years) with the dominant complaints of infertility (56.9%). Similarly, most (80.6%) cases presented with varicocele on left side while only 6.9% patients presented with bilateral varicocele.

Regarding incidence of postoperative outcome, Pini Prato A et al[25] evaluated the

effectiveness of laparoscopic procedure in a long-term prospective study and found 90% successful outcome with regard to improvement in symptoms and testicular catch up growth, however, they recorded that at least 15% of patients required an additional procedure during the 9-year follow-up period and 12% of these procedures were for postoperative hydrocelectomy. Similarly,Niyogi A et al[26], in a retrospective analytical study over a 10-year period encountered a recurrence rate of 16% for laparoscopic technique and 17% recurrence rate for the open Palomo technique, therefore, they have concluded that best results are achievable by the open technique. Mendez-Gallart R et al[27] evaluated the outcome of laparoscopic technique in terms of hydrocele formation and found postoperative hydrocele formation in 13.5% of patients. They have concluded that though laparoscopy is a safe procedure for varicocelectomy, it is associate with postoperative hydrocele formation. In light of these studies, our results are in close agreement. We found that though overall complication rates were higher for the open procedure (50% versus 26.7% for open and laparoscopic techniques, respectively), the recurrence rates were quite similar between the two studies (11.9% versus 10.3% for open and laparoscopic technique, respectively). Hydrocele formation was also similar in both groups (14.3% versus 13.3% for open & laparoscopic).**Table 2** We additionally found that the open technique was associated with 7.3% rate of postoperative epididymitis and 11.9% rate of postoperative scrotal haematoma. **Table 2**In our study, about 75% of patients achieved spontaneous resolution of their hydrocele within two weeks and only 2 (25%) patients required additional procedure for hydrocelectomy. All scrotal haematomas resolved spontaneously without surgical draining.

Keeping in view these findings of international studies and taking into consideration our findings, it is evident that though laparoscopic procedures are safe due to their lower invasiveness profile, it is also noteworthy that both open and laparoscopic procedures are associated with similar complication and recurrence rates.

The major weakness of our study is its retrospective nature. A large prospectively conducted study preferably with randomisation of the patients and blinding of the investigators would be a good step to better identify the procedure with more favourable outcome.

Conclusions

Varicocele is a commonly encountered disorder especially in the young male patients. Laparoscopic and open Palomo techniques are the widely available procedures for surgical intervention. Overall incidence of complications is higher in the open group. Though laparoscopic technique is better due to its minimally invasive profile, the recurrence rates are similar for both and selection of the surgical procedure should be tailored to the expertise of the surgeon and patient preference. Postoperative scrotal haematoma and majority of hydroceles respond to conservative treatment and only a quarter of them needs surgical repair.

Declarations:

This study was conducted in Naseerullah Baber Teaching Hospital and Hayatabad Medical Complex Peshwar, after approval from the Ethics Committee and requisite authority.

Authors Contribution:

Ashfaq Ur Rehman, Principal investigator, Lead Author

Muhammad Alam, Co-Author, Data Collection
Siddique Ahmed, Co-Author, Data Collection
Muhammad Ifitkhar, Co-Author, Data Capture form, Methodology
Sohaib Ali, Data Analysis, Background and Editing

Conflict of Interest:

There are no conflict of interest by all the authors concerned in study execution and conclusion.

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