Original Article

Surgery Section

A Prospective Randomized Controlled Trial Complains Open Pyeloplasty and Laparoscopic Pyeloplasty for Ureteropelvic Junction Obstruction (UPJO): Subjective Outcome

SRINIVAS K.K., UPPIN I.V., NERLE R.B.

ABSTRACT

Background: A study was conducted at the KLES hospital and MRC, Belgaum, for a period of 1 year from April 2004 to March 2005.

Objectives: To compare the efficacy of open pyeloplasty and laparoscopic pyeloplasty in the treatment of primary ureteropelvic junction obstruction with regards to the subjective outcome.

Materials and Methods: A total of 30 patients of congenital UPJO was evaluated and operated. All the 30 patients were randomized into two groups of 15 each. One group formed the open pyeloplasty group and the other formed the laparoscopic pyeloplasty group. All the patients were assessed for the subjective outcome post-operatively and all the patients were followed up for a minimum of 3 months. The results were analyzed by using the Student's paired and unpaired tests

Results: The mean age group, the laterality of involvement of the kidney and the sex ratio were almost similar between the two groups. The pre-operative pain and the activity levels were almost similar and comparable between the 2 groups. But, there was a significant post-operative improvement in the pain and the activity level in each group. In our study, we found that the improvement in the pain and the activity level post-operatively was much better in the laparoscopic pyeloplasty group patients as compared to those in the open pyeloplasty group patients. The time period when oral feeds were started and the drain was removed, was slightly more in the laparoscopic group, owing to the transperitoneal approach. There was no conversion to open procedure done in any of laparoscopic cases. The post-operative cosmesis was better inthe laparoscopic pyeloplasty patients as compared to the open pyeloplasty patients.

Conclusion: Our study was done on a small number of patients and the post-operative follow up was only for 3 months. It is difficult to draw conclusions from such a study. Hence, a large randomised controlled trial with a long period of follow up studies are needed to establish the role of laparoscopic pyeloplasty in the treatment of UPJ obstruction. The potential advantages of laparoscopic pyeloplasty over open pyeloplasty are decreased post-operative pain, a shorter period of hospitalisation, a short convalescence and improved cosmesis. Laparoscopic pyeloplasty is a technically challenging procedure and it is still in its infancy. It is being practised at only few medical centres around the world. With the recent technological advances, laparoscopic pyeloplasty has become a valid alternative to endoscopic pyelotomy and open pyeloplasty.

Key Words: Urology, Urosurgery, PUJ

INTRODUCTION

Many treatment options exist for the management of UPJ obstruction. Open pyeloplasty has a high success rate and it has been considered as the gold standard. But significant post-operative pain and a long recovery time period are related to the open pyeloplasty surgeries. In an attempt to minimize the post-operative morbidity of open surgical UPJ correction, many minimally invasive options have been developed. These include balloon dilatation, antegrade endopyelotomy, retrograde endopyelotomy, acucise endopyelotomy and laparoscopic pyeloplasty [1]. Laparoscopic pyeloplasty was first reported in 1993, both by Schuessler and co workers and by Kavoussi and Peters, who utilized the dismembered pyeloplasty technique [2]. During the last decade, advances in the endourological techniques have resulted in significant progress in the development of minimally invasive surgical procedures for treating UPJ obstruction [3]. The combination of less post-operative morbidity, improved cosmesis, shorter convalescence and comparable operative success rates has lured many patients away from the gold standard of open pyeloplasty. Only few retrospective studies have been conducted to compare laparoscopic and open pyeloplasty. The success rates are comparable for laparoscopic pyeloplasty and open pyeloplasty [3].

OBJECTIVES

To compare the efficacy of laparoscopic pyeloplasty v/s open pyeloplasty in the treatment of primary UPJ obstruction with respect to the SUBJECTIVE OUTCOME (Post-operative pain, activity level and time when oral feeds were started.)

MATERIALS AND METHODS

The present study was a prospective randomized control trial which compared laparoscopic pyeloplasty and open pyeloplasty in the treatment of primary ureteropelvic junction (UPJ) obstruction, which was conducted in the Department of Urology, KLES hospital

and MRC, Belgaum, during the period of 1 year from April 1004 to March 2005. A total of 30 patients were evaluated and operated for primary UPJ obstruction. They formed the clinical material for our study. Clearance from the ethical committee of the institution was obtained before the start of the study.

Source of Data

All the cases of primary UPJO of any age group which reported to the Department of Urology, KLES Hospital Belgaum.

Method of Collection

- Sample size – 30 patients.
- Sampling procedure: A total of 30 patients was selected and randomized into 2 groups of 15 each. 15 patients underwent open pyeloplasty and 15 patients underwent laparoscopic pyeloplasty.

Follow-up

All the patients were followed-up for a period of minimum 3 months to assess the subjective outcome. Routinely, in the uncomplicated cases, ureteric stent removal was done at 6 weeks. The total study period was 15 months.

Selection criteria

a. Inclusion criteria

All the patients of primary UPJO of any age group who were diagnosed clinically and/or radiologically (including both symptomatic and asymptomatic patients).

b. Exclusion criteria:

i. Patients with secondary UPJO.
ii. Patients with long segments of UPJ obstruction in which a normal caliber proximal ureter could not be brought to the renal pelvis without causing a lesion.
iii. Patients with urinary tract infection and a huge capacity pelvic.
iv. General contraindications for laparoscopic surgery (e.g. morbid obesity, major bleeding disorders, unacceptable anaesthesia risks and patients who do not tolerate the pneumoperitorium).
v. Patients who were unfit for surgery due to co morbid medical conditions.
vi. Redo surgeries or failed pyeloplasty.

All the patients were evaluated in detail by randomization. The diagnosis of primary UPJO was firmly established in all the patients, based on their history, physical examination, renal sonography and scintiography. The risks of the operation were fully explained to the patients and their parents and these included post-operative infection, bleeding, failed pyeloplasty, the need to convert to open surgery in case of laparoscopic pyeloplasty, damage to other viscera and adhesion formation.

The following investigations were done in all the patients.

1. Blood – complete haemogram, BT, CT
2. Urine – Routine Microscopy
3. Minirenals – RBS, B-Urea, S-Creatinine, S-Electrolytes
4. Serology –HIV, HBSAg
5. X-ray KUB
6. Renal USG
7. IVP
8. 99 mTc- DTPA scan.
9. CT scan / MR-Urogram (selected patients) of KUB.
10. Chest X-ray and ECG.

A prior fitness certificate was taken from a physician/paediatrician. The consent for the surgery was taken from the patients or the patients parents. An enema was administered on the night before the surgery to ensure that the colon was empty.

Anaesthesia

All the patients were operated under general anaesthesia. A retrograde pyelogram was done in all the patients before the surgery to delineate UPJO and to rule out other associated anomalies such as VUR (vesico-ureteral reflux). The patients were catheterized and the catheter was left on free drainage during the operation. Intra operation antibiotics were administered to minimize the risk of infections.

Position

The patients were put in the lateral position and were secured by placing a sand bag to support their backs. They were further stabilized by strapping their iliac crests to the operating table with adhesive bandages . They were placed as close as possible to the edge of the operating table.

Surgical technique

1. Anderson Hynes dismembered open pyeloplasty.
2. Laparoscopic Anderson – Hynes pyeloplasty.

Post-operative care

1. The drain was removed in less than 5 CC/ 24 hrs
2. The catheter was removed the next day
3. Oral fluids and feeding were started at the appearance of peristaltic bowel sounds.

Follow-up

1. In uncomplicated cases, the actual stent was removed after 6 weeks.
2. All the patients were followed up for urinary tract infection and renal scintigraphy was repeated at 3 months.

Assessment of the subjective outcome: The subjective outcome of these 2 groups was assessed, based on the response to the pain analog and the activity questionnaire of Nadler et al[4]. This questionnaire assessed the perceived pre-operative and post-operative pain on a scale of 0 (no pain) to 100 (worst pain) and also the activity levels on a scale of 0 (bed rest) to 100 (full/unrestricted). In children who were less than 6 yrs of age, a pictoral pain analog scale was used and the questionnaire was given to their parents to mark. All the patients received the same questionnaire. The patients were asked to comment on the pain and the activity level at the time of surgery and at the time of follow-up for the ureteral stent removal, usually after 6 weeks of surgery. The pre-operative assessment of the pain was based on memory and the post-operative assessment was based on the current status. The mean differences between the pre-operative and the post-operative pain and the activity scores were compared by using paired‘t’ tests.

The analog pain and the activity questionnaire which assessed the pre-operative and the post-operative pain and the activity:

1. Please mark on the following scale the level of discomfort you experienced before your procedure

0_____ 100

(no pain) (worst pain)

2. Please mark on the following scale the level of discomfort you are experiencing now, (6 weeks after the procedure)

0 _____100

(no pain) (worst pain)

3. If before your procedure, your discomfort level was 100%, what is your current level of discomfort?

_____(0-100%)

4. Please mark on the following scale your level of activity before your procedure

0 _____100

(bed rest) (full activity)

5. Please mark on the following scale your level of activity after the procedure (6 weeks).

0 _____100

(bed rest) (full activity)

RESULT

A total of 30 patients with primary UPJO who attended the Department of Urology, KLES and MRC, Belgaum, during a period of 1 year from April 2004 to March 2005 were selected for the study. All the 30 patients were randomized into 2 groups of 15 each. 15 patients underwent open pyeloplasty and this formed the open pyeloplasty group and the remaining 15 patients underwent laparoscopic pyeloplasty, who formed the laparoscopic pyeloplasty group. All the cases were followed up for a minimum of 3 months.

Sex incidence

Out of 15 patients in the open pyeloplasty group, 11 patients were males and 4 were females and out of 15 patients in the laparoscopic group, 11 were males and 4 were females.

Sex	Open pyeloplasty (n=15) group	Percentage (%)	Lap pyelo-plasty (n=15) group	Percentage (%)
M	11	73.3%	11	73.3%
F	04	26.6%	04	26.6%

[Table/Fig-1]: Sex Incidence of the two groups

Laterality

Out of 15 patients in the open pyeloplasty group, 4 had primary UPJO in the right kidney, 9 had it in the kidney and 2 had B/L UPJO. Out of 15 patients in the laparoscopic pyeloplasty group, 6 had primary UPJO in the right kidney, 07 had it in the left kidney and 2 had B/L UPJO.

Laterality	Open pyeloplasty (n=15) group	Percentage (%)	Lap pyeloplasty (n=15) group	Percentage (%)
Right	04	33.33%	06	40%
Left	09	55.33%	07	46.6%
B/L	02	13.33%	02	13.33%

[Table/Fig-2]: Laterality of the two groups

Age

The average age of the patients who underwent open pyeloplasty was 22.83 yrs (range-5mts-48yrs) and that of those who underwent laparoscopic pyeloplasty was 20.42 yrs (range-8 mts to 65 yrs).

	Open pyeloplasty group n=15	Lap pyeloplasty group n=15
Average (yrs)	22.83 yrs	20.42 yrs
Range	5 mts-48 yrs	3 mts- 65 yrs

[Table/Fig-3]: Age Distribution of the two groups

Symptoms

Most of the patients presented with pain in the loin region or an asymptomatic mass per abdomen or both.

Presentation	Open group n=15	%	Lap group n=15	%
Pain	12	80%	09	60
Mass per abdomen	02	13.3	05	33.33
Both	01	6.6	01	6.66

[Table/Fig-4]: Symptoms of the two groups

Associated anomalies

Out of 15 patients in the open pyeloplasty group, one patient had a right solitary kidney (an absent left kidney). Out of 15 patients in the laparoscopic pyeloplasty group, one patient had a horse shoe kidney with a contracted kidney on the contralateral side and hypertension.

Ass anomaly	Open pyeloplasty	Lap pyeloplasty
R Solitary kidney	01	–
Horseshoe kidney	–	01

[Table/Fig-5]: Associated Anamolies of the Two Groups

Post-operative subjective outcome

The subjective outcome of the 2 groups was assessed, based on the response to the pain analog and the activity questionnaire of Nadler et al.

	Mean (range) Open pyeloplasty		Lap pyeloplasty
1	Pain		
	- Pre-operative	62.66 (0-100)	59.00 (0-100)
	- Post-operative	18.0 (0-100)	5.33 (0-100)
	- Difference	44.66	53.67
2	Activity		
	- Pre-operative	54.66 (0-100)	48.66 (0-100)
	- Post-operative	90.66 (0-100)	96.33 (0-100)
	- Difference	40	47.67

[Table/Fig-6]: Pre-operative and post-operative pyeloplasty analog pain and activity scores

DISCUSSION

The gold standard for the repair of UPJ obstruction is open pyeloplasty and the best clinical results have been reported with the complete dismembering techniques like the Anderson-Hypes procedure. The success rates of this technique are reported to be 90-100% [5,6]. Open surgical techniques result in significant per- and post-operative morbidity, post-operative pain and scar

formation. In the hope of decreasing the surgical morbidity which is associated with the open approach, several minimally invasive procedures have been introduced during the past two decades, specifically antegrade and retrograde endopyelotomy [7,8,9]. The cumulative experiences with these procedures have shown a fairly good success rate (61-89%) and a significant risk of bleeding. The minimal invasive endoscopic procedures were reported to have a good initial success rate. However, long-term results, even in the highly selected cases, are poor.

Endopyelotomy became popular in the 1980s and 1990s as a minimally invasive technique with low complication rates, relatively short operating times and a short convalescence period.

More recently, the laparoscopic procedures which are used to treat UPJO have combined the advantages of minimally invasive procedures. A high degree of safety and high success rates have been obtained with open surgical procedures. Since the end of the last decade, laparoscopic pyeloplasty has become increasingly popular. The success rates have been quoted to be about 87-100% [10,11,12]. This procedure allows the identification of the crossing vessels, excision of the diseased UPJ plus or minus a reduction pyeloplasty and a watertight anastomosis. In addition, the analgesic requirement, the hospital stay and the recovery period are considerably reduced as compared to the open pyeloplasty. Schuessler et al. first introduced laparoscopic pyeloplasty in 1993 and a variety of authors have reported on their clinical experiences with respect to this promising new technique. The techniques which have been described, differed mainly in the way of performing the pyeloplasty by utilizing either a complete dismembering or a non-dismembering technique. Laparoscopic pyeloplasty can be performed via a retroperitoneal or a transperitoneal approach. Equivalent success rates have been quoted in the literature for both these methods. In our study, we used a transperitoneal approach for all the patients in the laparoscopic pyeloplasty group, as this approach offered ease in identifying, dissecting and mobilizing the intra-abdominal structures, while the potential disadvantages included a prolonged ileus, adhesion formation, and injury to the adjacent viscera.

The major advantage of the retroperitoneoscopic approach was that it provided a direct route to the UPJ and thus allowed access without interference from the intra-abdominal structures. However, the working space was limited, and the absence of anatomic landmarks made the dissection more cumbersome. The greatest drawback which was associated with these treatments was the risk of vascular injury. Sampaio has shown that in 72.2% of the cases, the crossing vessels could be found either anterior or posterior to the UPJ. These vessels could be injured during the UPJ incision without a prompt intra-operative recognition, leading to significant bleeding. Faerber et al. reported two bleeding complications in their series of 32 patients (6.2%). Merety K et al. reported bleeding that required transfusion in 95 patients and in 16% of their patients in their series of antegrade and retroantegrade endopyelotomies respectively.

The results of laparoscopic pyeloplasty from several institutions which reported on the adult series, suggested that this procedure was a viable alternative to both open and endoscopic procedures. With the increased training and experience, the success rate has clearly exceeded that of endoscopic approaches and it is similar to that of open pyeloplasty. The potential advantages of laparoscopic pyeloplasty over open pyeloplasty are decreased post-operative pain, shorter hospitalization, short convalescence and improved cosmesis. An important caveat, as was concluded by Bauer et al[13], is that neither open nor laparoscopic pyeloplasty can universally guarantee complete pain relief. Laparoscopic pyeloplasty in children is even more technically challenging than that in adults because of the smaller operative space and the need for finer suture material. However, laparoscopic pyeloplasty has been demonstrated to be feasible and to have satisfactory early results. After a decade, laparoscopic pyeloplasty has emerged as a durable elective technique for the management of UPJ obstruction.

Laparoscopic pyeloplasty is continuing to progress and it offers promise for some of the most challenging circumstances. As the technology advances and as the clinical experience increases, this technique may universally replace open pyeloplasty as the gold standard.

In our present study, the total 15 patients who underwent open pyeloplasty, were in the age group of 5 months to 54 yrs (mean age = 22.82yrs) and the male to female ratio was 2.75:1. The laterality, that is the involvement of the right and left kidney was in the ratio of 1:2.25 and 2 cases had bilateral involvement, (13.33%). Both had undergone open pyeloplasty earlier in our institute. The associated anomalies were found in 2 of the 15 patients, (13.33%). One of those had a double moiety ureter on the left side with lower moiety meter UPJO and the other patient had a right solitary kidney.

The other 15 patients who underwent laparoscopic pyeloplasty by the transperitoneal approach, were in the age group of 9mts – 65 yrs (mean age = 20.42yrs) and the male to female ration was 2.75:1. The laterality, that is the involvement of the right and the left kidney was in the ratio of 1:2.25 and 2 cases had bilateral involvement (13.33%). Both had undergone open pyeloplasty, one at our institute and the other had undergone it elsewhere. The associated anomalies were found in one patient in the laparoscopic pyeloplasty group (6.66%), who had a horseshoe kidney. In the literature, it is mentioned that UPJO occurs more commonly in males than in females, that the ratio exceeds 2:13 and that left sided lesions pre-dominate (approximately 67%). Bilateral UPJO is present in 10-40% of the cases and our patient demographics were in concordance with the reports in the literature.

The pain and the activity level were assessed both pre-operatively and by using a pain analogy scale and the activity questionnaire of Nadler et al. in both the groups. The pain and the activity level were assessed pre-operatively just one day prior to the surgery and post-operatively, the pain and the activity level were assessed after 6 wks at the time of the ureteral stent removal. The statistical analysis was done by using the Students unpaired and paired‘t’ tests.

The mean pre-operative pain level in the open pyeloplasty group was 62.66% and the mean post-operative pain level at 6 weeks was 18%. The mean pre-operative activity level was 54.66 and the mean post-operative activity level at 6 weeks was 90.66. The mean pre-operative pain level in the laparoscopic group was 59.0 and the mean post-operative pain level at 6 weeks was 5.33. The mean pre-operative activity level was 48.66 and the mean post-operative activity level at 6 weeks was 96.33. From the results, we could assess that the difference between the mean pre-operative pain levels of the open and the laparoscopic pyeloplasty groups was not significant and that the difference between the mean pre-operative activity levels of both the groups and the difference between the post-operative activity levels of both the groups were not significant. The difference in the pain level between the

open and the laproscopic pyeloplasty groups was significant and the difference between the activity levels of both the groups was significant. The results concluded that the laparoscopic pyeloplasty group patients had significant improvement in the pain and the activity level post-operatively than those patients who had undergone open pyeloplasty.

In the laparoscopic pyeloplasty group, the conversion to open pyeloplasty was not done in any patient. No anastomotic stricture was observed in any patients. The success rate was 100% in both the groups. The mean time when oral feeds were started in the open pyeloplasty group was 1.4 days and it was 2.33 days in the laparoscopic pyeloplasty group.

In the literature, only few studies have compared the objective and subjective out comes between open versus laproscopic pyeloplasty. A study which was conducted by John J Bauer and Louis R Kovoussi [13] compared laparoscopic vs. open pyeloplasty with respect to the objective and subjective outcomes. The results showed that out of 42 laparoscopic group patients, 90% were pain free and that 62% showed significant improvement in the flank pain 2 patients had minor improvement and 2 had no improvement in the pain. Surgery failed in only 1 patient with complete obstruction. A patient UPJ was demonstrated in 98% of the laparoscopic group patients. In the most recent radiographic study, the mean follow-up was found to be 15 months for the 35 open surgery group patients. 91% were found to be pain free, 31% patients significantly improved after the surgery, one patient had only minor improvement and 2 became worse.

CONCLUSION

The results of laparoscopic pyeloplasty from several institutions which reported on the adult series suggested that this procedure was a viable alternative to both the open and endoscopic procedures. With the increased training and experience, its success rate has clearly exceeded that of endoscopic procedures and it is similar to that of open pyeloplasty. After a decade, laparoscopic pyeloplasty has emerged as a durable elective technique for the management of UPJ obstruction. Laparoscopic pyeloplasty is continuing to progress and it offers promise for some of the most challenging circumstances. As the technology advances and as the clinical experience increases, this technique may universally replace open pyeloplasty as the gold standard.

REFERENCES

[1] D Duane Baldwin, Jennifer A Dunbar, Nancy Wells, Elspeth M, Mc Dougall. Single centre comparison of laparoscopic pyeloplasty, acucise endopyelotomy and open pyeloplasty. *Journal of Endourology* Apr 2003; 17.

[2] Steven B Streem, Jenny J Franke, Joseph A, Smith JR. *Campbell's Urology.* Second edition. Vol 1 38-40, Vol 3 478-89.

[3] Hartley G, Cileton JR, George W Kalpan. Ureteropelvic-junction obstruction. *King's Infant Children Urology*. 3rd edition: 19-29.

[4] Nadler, Pearle, Nakada, Clayman RV. Access endopyelotomy. Assessment of the long-term durability. *Journal of Urology* 156: 1094-96.

[5] Notley RG, Beaurgie JM. The long term follow up of Anderson-Hynes pyeloplasty for HN. *British Journal of Urology* 1973; 45: 464-67.

[6] Persky L, Kraurse JR, Boltuch RL. Initial complications and late results in dismembered pyeloplasty. *Journal of Urology 1977*; 118: 162-65.

[7] Faerber GJ, Richardson TD, Farah N, et al. Retrograde treatment of UPJO by using the ureteral cutting balloon catheter. *Journal of Urology* 1997; 157: 454-58.

[8] Quillin SP, Brink JA, Heiken JP, et al. Helical CT angiography for the identification of the crossing vessels at the UPJ. *AJR American Journal of Roentgenology* 1996; 116: 1125-30.

[9] Brooks JD, Kouvossi LR, Preminger GM, et al. Comparison of the open and endourological approaches to UPJO. *Journal of Urology* 1995; 46: 791-95.

[10] Pattaras JG, Moore RG: Laparoscopic pyeloplasty. *Journal of Endourology* 2000; 14: 895-904.

[11] Moore RG, Averch TD, Schulam PG, et al. Laparoscopic pyeloplasty; experience with the initial 30 cases. *Journal of Urology* 1997; 157: 459-62.

[12] Jarrett TW, Chan DY, Charambura TC, et al. Laparoscopic pyeloplasty: the first 100 cases. *Journal of Urology* 2002; 167: 1253-56.

[13] Bauer JJ, Bishoff JT, Moore RG, Chen RN, Iverson, et al. Laparoscopic versus open pyeloplasty: Assessment of objective and subjective outcome. *Journal of Urology* 1999; 162 (3-1): 692-95.

AUTHOR(S):

1. Dr. Srinivas K.K.
2. Dr. Uppin I.V.
3. Dr. Nerle R.B.

PARTICULARS OF CONTRIBUTORS:

1. MS. Surgery, Assistant Professor, Department of General Surgery, SDMCMSH, Dharwad.
2. MS Surgery, MCH Urology, HOD and Professor, Department of Urology JNMC, Belgaum.
3. MS Surgery, Retd HOD and Professor, JNMC, Belgaum

PLACE OF STUDY

Department of Urology
KLES Hospital and MRC, Belgaum

NAME, ADDRESS, TELEPHONE, E-MAIL ID OF THE CORRESPONDING AUTHOR:

Dr. Srinivas K.K.
Phone: 9482235235
E-mail: drsrinivaskalabhavi@yahoo.co.in

DECLARATION ON COMPETING INTERESTS:

No competing Interests.

Date of Submission: **Aug 30, 2011**
Date of peer review: **Oct 14, 2011**
Date of acceptance: **Nov 18, 2011**
Date of Publishing: **Dec 25, 2011**