

LAPAROSCOPIC VERSUS OPEN RETROPERITONEAL BILATERAL VARIX LIGATION FOR OBESE PATIENTS PRESENTING WITH PRIMARY SUB-FERTILITY: A RANDOMIZED COMPARATIVE STUDY

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Objectives: To compare the outcome of laparoscopic versus open varicocelectomy in sub-fertile obese men presenting with bilateral testicular varicoceles.

Materials and Methods Forty obese (body mass index > 30) primary sub-fertile males with bilateral varicoceles were selected for this study and randomly subjected to either laparoscopic varicocelectomy (Group I, n=20) or high retroperitoneal open ligation (Group II, n=20). Semen analysis was performed preoperatively and three months or more postoperatively. Scrotal duplex was done for each case preoperatively and 6 months post-operatively.

Results The average operative time in Group I and Group II was ~77.3 minutes and ~58 minutes, respectively ($P < 0.05$). Analgesia requirements were significantly less in the laparoscopic group. Only one patient of Group I developed subcutaneous haematoma, while in Group II three developed wound infections and six patients developed wound seroma. The average hospital stay of the patients of Groups I and II was 8.4 hours and 52 hours, respectively ($P < 0.05$). The patients of Group II returned to their usual daily activities after an average of 5.3 days, while the patients of Group I needed an average of 8.4 days ($P < 0.05$). Hydrocele occurred in none of the patients of Group I and in three patients (15.7%) of Group II ($P < 0.05$). Recurrence of the

varicocele occurred in none of the patients of Group I, but in three patients (15.7%) of Group II ($P < 0.05$). The semen parameters improved after surgery in both groups. The mean improvement in sperm concentration was ~ 32.5 million sperm/ml in Group I and ~25 million sperm/ml in Group II ($p > 0.05$). The mean improvement in the total sperm count was ~ 96 million sperms in Group I and ~92 million sperms in Group II ($p > 0.05$). The mean percentage of improvement in sperm motility was ~ 16.5% in Group I and 14.1% in Group II ($p < 0.05$). The mean decrease in the percentage of abnormal forms was ~20% in Group I and ~5.5% in Group II ($p < 0.05$). Moreover, the quality of motility (grades) improved significantly after laparoscopic varix ligation, to a higher extent than after open surgery.

Conclusion: The laparoscopic approach is an excellent option for varix ligation in obese patients. Morbidity is less and convalescence is shorter compared to open surgery. A particular advantage of laparoscopy over conventional surgery is the possibility of treatment of bilateral varicoceles through the usual three laparoscopic ports. In this study, improvement in some semen parameters was significantly better following laparoscopic varix ligation. This may be explained by the better view and magnification offered by laparoscopy.

Key Words: varicocele, laparoscopy

INTRODUCTION

The association between the presence of a varicocele and a decline in semen parameters has been documented in the literature^{1,2,3}, and an improvement in semen parameters has been reported to be significant following varico-

varicocelectomy⁴⁻⁸. The treatment options for varicocele are spermatic vein sclerotherapy or embolization, classical surgical treatment via the scrotal, high retroperitoneal or inguinal approach, microsurgical varicocelectomy and laparoscopy.⁹⁻¹³ Although the microscopic sub-inguinal approach is gaining acceptance as the

Table 1: Varicocele Grades in the Patients of this Study

	Group I* (n=20)		Group II** (n=20)		P Value***
	Right	Left	Right	Left	
	No. (%)	No. (%)	No. (%)	No. (%)	
Grade I	3 (15%)	2 (10%)	4 (20%)	3 (15%)	>0.05
Grade II	6 (30%)	8 (40%)	9 (45%)	10 (50%)	>0.05
Grade III	11 (55%)	10 (50%)	7 (35%)	7 (35%)	>0.05

* Group I: laparoscopic varicocelectomy; ** Group II: open (Palomo) varicocelectomy

*** Chi-square test: $p > 0.05$ = insignificant; $p < 0.05$ = significant

preferred treatment of varicoceles, the need for sophisticated instruments and the cost of the procedure limit its wide-spread application. Consequently, the retroperitoneal approach (high ligation) is still the preferred treatment for varicoceles in many centers. All treatment options are applicable for average as well as obese individuals. However, obese patients are generally more liable to intraoperative and postoperative morbidity than average individuals. When the classical Palomo operation is undertaken in such patients, a larger surgical incision is required and the exposure of the spermatic vessels is relatively difficult. Therefore, the operative time is often longer when compared to a similar procedure being performed on a slim or average-built individual. Consequently, a relatively high rate of morbidity and a longer convalescence are both expected following classic retroperitoneal varicocelectomy in obese patients.

We believe that an operation like retroperitoneal varix ligation when carried out from "within" i.e. through laparoscopy would be less morbid than the classic approach in obese patients. In this work we present a prospective randomized comparison between the two approaches in the management of primary varicoceles in sub-fertile obese men.

PATIENTS AND METHODS

Forty obese primary sub-fertile males with bilateral varicocele were selected for this study which was carried out between February and December 2001. A patient was considered obese when his body mass index exceeded 30. The selected patients were randomly sub-

jected to either laparoscopic varicocelectomy (Group I) or high retroperitoneal ligation (Group II). Randomization was performed by the "Block Randomization" technique. Ten blocks of patients were created with each block containing four patients (two from each group), and the patients within the group were haphazardly arranged. Consequently each group included 20 patients. Their age ranged from 24 to 41 years (mean 26.3 years). The body mass index ranged from 32.2 - 42.4 (mean 34.7). All patients had suffered from infertility for at least one year.

The varicoceles were bilateral in all cases. Both groups were statistically similar regarding age and body mass index. The mean age in Groups I and II was 25.8 ± 4.8 years and 27.3 ± 6.6 years, respectively ($t = 0.893$, $p > 0.05$). The mean body mass index in Groups I and II was 32.4 ± 6.1 and 34.6 ± 9.3 , respectively ($t = 1.4$, $p > 0.05$). The distribution of varicocele grades among both groups was not statistically different. (Table 1)

The semen analysis was performed preoperatively and three months or more postoperatively. Semen specimens were collected by masturbation after a three-day abstinence period and analyzed within one hour of collection. Semen analysis included the volume of ejaculate, the sperm concentration (million sperm per ml), the percent motility, the grade of motility and the percentage of morphologically normal sperms. Motility was graded 0-none, 1-poor, 2-fair, 3-good and 4-excellent.

The preoperative semen parameters were comparable among both groups with no statistically significant differences.

Table 2: Operative and Postoperative Data

	Group I* (n=20)		Group II** (n=20)		P Value***
	Mean (\pm SD)	Range	Mean (\pm SD)	Range	
Operative time (minutes)	77.3 \pm 12.4	54 – 110	58.1 \pm 10.8	42 – 97	<0.05
<u>Analgesia</u>					
Pethidine (mg)	70.4 \pm 8.2	50 – 150	147.3 \pm 12.8	100 – 200	<0.05
Parenteral NSAID# (dose)	3.2 \pm 1.9	2 – 8	8.6 \pm 2.4	4 – 12	<0.05
Oral NSAID (dose)	8.4 \pm 3.2	4 – 17	21.2 \pm 1.8	10 – 28	<0.05
Hospital Stay (hours)	8.4 \pm 10.3	6 – 24	52.5 \pm 20.4	24 – 168	<0.05
Time to return to daily activities (days)	5.3 \pm 1.7	3 – 12	8.4 \pm 2.1	5 – 14	<0.05

* Group I: laparoscopic varicocelectomy; ** Group II: open (Palomo) varicocele

*** Independent Sample t-test: $p > 0.05$ = insignificant; $p < 0.05$ = significant

NSAID = non-steroidal anti-inflammatory drug

The comparison of the preoperative and postoperative semen analysis was based on the mean values for each semen parameter for a particular patient.

Scrotal duplex was done for each case preoperatively and six months or more postoperatively. Mainly three aspects were examined: testicular size, confirmation of the varicocele (or detection of recurrence) and identification of a hydrocele.

Operative Technique

For the patients of Group I, laparoscopic varicocelectomy was carried out through three ports: one camera port at the umbilicus and two 12 mm ports each just lateral to the ipsilateral rectus muscle at a level slightly below the umbilicus. After all trocars were fixed and the laparoscope introduced, the peritoneal cavity was explored and the spermatic vessels were identified just entering the internal ring. The peritoneal incision was carried out lateral to the spermatic vessels starting at a point one cm proximal to the internal ring and extended proximally for a three cm distance. If the vessels were not identified due to extensive extraperitoneal fat, a pull on the testis would result in a noticeable pull on the vessels and, hence, the peritoneal incision could be carried out. Starting at the midpoint of the peritoneal incision the peritoneum was further transected over the cord to make a T-shape incision. At this moment the spermatic veins were identi-

fied and each vein was dissected and freed from the surrounding tissue. Each vein was completely skeletonized in order to avoid ligation of the lymphatic vessels as much as possible. Each vein was consequently double clipped and divided. In each of the 40 laparoscopic varicocelectomies the artery was identified and spared except in three cases. In some cases a flush with papaverine was used to demonstrate the arterial pulsation.

The patients of Group II were operated following the Palomo principle. An incision just above the level of the internal ring was done. After the anterior abdominal wall muscles were incised and the peritoneum retracted, the retroperitoneal space was entered, and the spermatic veins were usually identified adherent to the peritoneum. Complete dissection of each vein was done and then each was individually ligated and divided. The spermatic artery was searched for in every patient, but out of the 40 cases of open varicocelectomy the artery could be identified with certainty in four cases only.

The perioperative data, complications and changes in semen parameters were collected and statistically analyzed using the independent sample t-test and the Chi-square test.

The patients were followed up every three months for at least 6 months. The mean follow-up was 8.2 months (\pm 2.2) ranging from 6 – 9 months.

Table 3: Late Complications

Complication	Group I* (n=18)		Group II** (n=19)		P-Value***
	No.	(%)	No.	(%)	
Recurrence of varix	1	(5.6%)	3	(15.8%)	<0.05
Secondary hydrocele	0		3	(15.8%)	<0.05

* Group I: laparoscopic varicocelectomy; ** Group II: open (Palomo) varicocelectomy

*** Chi-square test: $p > 0.05$ = insignificant; $p < 0.05$ = significant

Table 4: Semen Parameters Before and After the Operation

Semen Parameters	Group I* (n=18)			Group II** (n=19)			P-Value***
	Preoperative mean (range)	Postoperative mean (range)	Mean Change	Preoperative mean (range)	Postoperative mean (range)	Mean Change	
Sperm Conc. (ml)	16.85 ± 3.8 (9.4 – 72.7)	49.6 ± 12.6 (11.8 – 95)	32.4 ± 16.8	19.3 ± 4.2 (11.4 – 96.4)	41.5 ± 8.1 (12.6 – 105)	24.8 ± 14.6	>0.05
Total Sperm Count	58.43 ± 16.5 (31.3 – 82.5)	167.7 ± 21.9 (36.1 – 195.6)	95.7 ± 26.4	49.2 ± 13.5 (27.8 – 105.3)	144.2 ± 16.2 (29.8 – 201.3)	91.8 ± 20.3	>0.05
% Motile Sperms	27.3 ± 4.2	42.5 ± 5.3	16.4 ± 3.1	24.5 ± 6.2	37.3 ± 6.9	14.1 ± 1.9	<0.05
% Abnormal forms	66.4 ± 9.8	47 ± 16.8	20.3 ± 2.7	53.7 ± 11.5	49.5 ± 13.2	5.4 ± 3.4	<0.05

* Group I: laparoscopic varicocelectomy; ** Group II: open (Palomo) varicocelectomy

*** Chi-square test: $p > 0.05$ = insignificant; $p < 0.05$ = significant

RESULTS

The average operative time in Groups I and II was 77.3 and 58 minutes, respectively. The average size of the incision in Group I patients was 1 cm for each of the laparoscopic port accesses. The average size of each incision in Group II patients was 8.3 cm. Postoperative analgesia was given on demand. The patients of Group I required an average of 70 mg pethidine, an average of ~3 doses of parenteral non-steroidal anti-inflammatory drug (NSAID) and an average of 8 doses of oral NSAID. The patients of Group II required an average of 147 mg pethidine, an average of ~9 doses of parenteral NSAID and an average of 21 doses of oral NSAID. The requirements for both narcotic and NSAID analgesia in Group II were significantly higher compared to Group I (Table 2).

The average hospital stay in the patients of Group I was 8.4 hours compared to 52 hours for the patients of Group II ($p < 0.05$). The time required to return to the usual daily activities was an average of 5.3 days in Group I and 8.4 days in Group II ($p < 0.05$) (Table 2)

There were no serious operative or postoperative complications. In Group I, a subcutaneous haematoma was encountered at a trocar site of one of the patients, while in Group II, complications were encountered in the form of wound infection in three and wound seroma in six patients.

As for the late complications, scrotal ultrasound performed six months or more after surgery revealed recurrence of the varicocele in 1 (5%) of the available 18 patients of Group I and in 3 (15.7%) of the available 19 patients of

Table 5: Sperm Motility Before and After the Operation

Motility Grade	Group I*			Group II**			P-Value***
	Preoperative	Postoperative	Change	Preoperative	Postoperative	Change	
4	3.7	6.2	2.5	4.2	5.6	1.3	<0.05
3	6.2	17.1	10.5	1.5	8.2	6.3	<0.05
2	9.8	13.4	3.5	8.1	9.5	1.6	>0.05
1	8.7	5.8	1.8	10.7	14	4.3	>0.05
0	72.7	57	14.6	75.5	62.7	12.4	<0.05

* Group I: laparoscopic varicocelectomy; ** Group II: open (Palomo) varicocelectomy

*** Chi-square test: $p > 0.05$ = insignificant; $p < 0.05$ = significant

Group II. Hydrocele formation occurred in none of the Group I patients, but in 3 (15.7%) of the available 19 patients in Group II. None of our patients developed testicular atrophy. The incidence of varicocele recurrence and hydrocele formation was significantly higher in the patients of Group II (Table 3).

The mean sperm concentration increased from 16.85 (± 3.8) million sperms per ml preoperatively to 49.6 (± 12.6) million sperms per ml postoperatively in Group I (laparoscopic group), accounting for a mean improvement of 32.4 (± 16.8) million sperms per ml. In Group II (open surgery group) the mean sperm concentration increased from 19.3 (± 4.2) million sperms per ml preoperatively to 41.5 (± 8.1) million sperms per ml postoperatively, accounting for a mean improvement of 24.8 (± 14.6) million sperms per ml. The difference in the improvement of sperm concentration between both groups was in favour of Group I but was statistically insignificant (Tables 4 and 5).

The mean total sperm count increased from 58.43 (± 16.5) million sperms preoperatively to 167.7 (± 21.9) million sperms postoperatively in Group I, accounting for a mean improvement of 95.7 (± 26.4) million sperms. In Group II it increased from 49.2 (± 13.5) million sperms preoperatively to 144.2 (± 16.2) million sperms postoperatively, accounting for a mean improvement of 91.84 (± 20.3) million sperms. The difference in the improvement of sperm count between the groups was in favour of Group I but was statistically insignificant.

The mean sperm motility increased from 27.3% ($\pm 4.2\%$) preoperatively to 42.5% ($\pm 5.3\%$) postoperatively in Group I, accounting for a mean improvement of 16.4% ($\pm 3.1\%$). In Group II, it increased from 24.57% ($\pm 6.2\%$) preoperatively to 37.3% ($\pm 6.9\%$) postoperatively, accounting for a mean improvement of 14.1% ($\pm 1.9\%$). The rate of improvement of sperm motility was significantly higher in Group I as compared to Group II ($p < 0.05$).

The percentage of abnormal sperms decreased from 66.3% ($\pm 10.2\%$) before surgery to 47% ($\pm 16.8\%$) after surgery in Group I, accounting for a mean decrease of 20.3% ($\pm 2.7\%$). In Group II, the percentage of abnormal sperms decreased from 53.7% ($\pm 11.5\%$) before surgery to 49.5% ($\pm 13.2\%$) after surgery, accounting for a mean decrease of 5.4% ($\pm 3.4\%$). The decrease in the percentage of abnormal forms was significantly better after laparoscopic varicocelectomy ($p < 0.05$).

Finally, the grades of sperm motility improved in both groups with a significantly higher rate of improvement in Group I (Table 5). In Group I, approximately 4% of the sperms had grade 4 motility, ~6% had grade 3, ~10% had grade 2 and ~7.5% had grade 1 motility while 72.5% were non motile (grade zero) preoperatively. This changed postoperatively to ~6%, 17%, 13%, 6% and 58% for grades 4, 3, 2, 1 and zero, respectively. In Group II, approximately 4% of the sperms had grade 4 motility, ~1.5% had grade 3, ~8% had grade 2 and ~11% had grade 1 motility, while ~75.5% were non motile preoperatively. This changed post-

operatively to ~5.5%, 8%, 9.5%, 14% and 63% for grades 4, 3, 2, 1 and zero, respectively.

The results of this study revealed that all semen parameters improved after varicocelectomy whatever the approach was. However, improvement after laparoscopic varix ligation was better than after open surgery. Nevertheless, the statistical significance was evident in favour of the laparoscopic procedure in only three aspects of the semen parameters, namely in the number of motile sperms, the quality (grade) of sperm motility and the percentage of abnormal forms.

DISCUSSION

The approach to varix ligation in treatment of male factor infertility has been a matter of controversy for decades. Although the microscopic subinguinal approach is gaining popularity as the most precise approach for the control of the testicular vein varicosities, certain factors still limit the acceptance of this approach. Among these are the need for a specific experience in microscopic surgery and the cost of the procedure. Moreover, there is a lack of definitive data based on controlled randomized studies that confirm the superiority of the microscopic subinguinal approach over conventional varicocele surgery in terms of improvement in semen parameters and pregnancy rates. For these reasons the retroperitoneal approach for varix ligation is still the approach of choice in many areas in the world.

The retroperitoneal approach has the advantage of isolating the internal spermatic veins proximally, near the point of drainage into the left renal vein. At this level, only one or two large veins are present and, in addition, the testicular artery has not yet branched and is often distinctly separate from the internal spermatic veins¹⁴. The sacrifice of the testicular artery at this point has virtually no other consequences¹⁵. However, since bilateral testicular artery ligation has been documented to occasionally produce azoospermia and testicular atrophy¹⁴, every effort should be made to spare the testicular artery.

Obesity poses a great problem for most urologic procedures, and there is no doubt that obese patients are significantly more liable to operative and postoperative complications than average individuals. An example of this is retroperitoneal varicocelectomy. Although the

operation per se is usually not a major procedure, a substantial surgical effort is usually required in obese patients. A larger incision is usually needed, the use of large abdominal retractors is usually necessary and the thick layer of fat makes the surgical field a deep one that increases the difficulty of the procedure. All these factors directly or indirectly increase the morbidity of surgery and prolong the convalescence period. This is usually multiplied when bilateral varicocelectomy is performed.

Bearing this in mind we have considered the laparoscopic approach for varix ligation in obese patients. We strongly believe that the laparoscopic approach, which was introduced in 1988^{16,17}, is a rather direct one for dealing with the spermatic veins. The veins are readily identified once the peritoneal cavity is entered, and with minimal dissection each vein can be identified and clipped. This procedure is not hampered by the thick pad of fat in the abdominal wall and avoids the large exposure required for such cases. It also precludes the use of retractors and spares much of the effort required in the classic open approach. In addition, the laparoscope possesses the important advantages of a wider view and excellent magnification; both aid greatly in identifying all the veins and sparing lymphatic vessels, thus avoiding to a great extent the two most common complications of the high approach, namely varicocele recurrence and hydrocele formation. The excellent view of laparoscopy helps to identify the spermatic artery which is usually not visible in approximately 90% of cases treated by the classic open approach¹⁸.

In this work, we carried out a prospective randomized comparison between the laparoscopic and classic open approach for varix ligation. The improvement in all semen parameters was better following laparoscopy compared to open surgery. However, these differences in improvement rates were statistically significant only regarding sperm motility (quantitatively and qualitatively) and the reduction of abnormal forms. Although in open surgery the operative time was shorter than for the laparoscopic approach by approximately 20 minutes, we believe that this is of minor concern, particularly if we have a higher post-operative morbidity following surgery as well as a higher demand for analgesia. Moreover, the hospital stay and convalescence period were shorter following laparoscopy. The incidence of both recurrent varicocele and hydrocele formation was significantly lower in the group treated

by laparoscopy than in the surgically treated group.

We believe that the results of this study justify the laparoscopic approach for obese men with varicoceles (particularly bilateral cases). Although technically more demanding and apparently more costly, yet the advantages of lower morbidity and better improvement in many semen parameters make it more acceptable than open surgery on a subset of obese patients with primary subfertility.

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RESUME

Laparoscopie Comparée à la Chirurgie Ouverte Rétro Péritonéale dans la Ligature de Varices chez des Patients Obèses Présentant une Hypofertilité Primaire : Etude Comparative Randomisée.

Objectifs: Comparer les résultats de la laparoscopie par rapport à la varicocœlectomie par chirurgie ouverte chez des patients obèses présentant une hypofertilité associée à une varicocèle bilatérale. **Matériel et Méthodes:** Quarante hommes obèses (index de masse corporelle > 30) présentant une hypofertilité primaire avec varicocèle bilatérale ont été sélectionnés pour cette étude randomisée. Ces patients ont bénéficié soit d'une varicocœlectomie laparoscopique (Groupe I n=20) soit d'une ligature haute par chirurgie haute rétro péritonéale (Groupe II n=20). Un spermogramme a été réalisé en préopératoire et 3 mois au moins en postopératoire. Un écho doppler scrotal a été réalisé dans les 2 groupes en préopératoire et à 6 mois postopératoire. **Résultats:** La durée moyenne de l'intervention était d'environ 77,3 minutes pour le Groupe I et de 58 minutes pour le Groupe II (P < 0.05). La de-

mande en analgésique était significativement moins importante dans le Groupe I. Seul un patient du groupe I avait développé un hématome sous cutané tandis que dans le Groupe II 3 patients avaient présenté une infection de la plaie opératoire et 6 patients des sérosités au niveau de la plaie. La durée moyenne d'hospitalisation était de 8.4 et de 58 heures respectivement pour les Groupes I et II ($P < 0.05$). Les patients étaient retournés à leurs activités quotidiennes habituelles après une moyenne de 5.3 jours pour le Groupe I et de 8.4 jours pour le Groupe II ($P < 0.05$). Il n'a pas été noté d'hydrocèle dans le Groupe I alors que 3 patients (15.7%) du Groupe II présentaient une hydrocèle ($P < 0.05$). Aucune récurrence de varicocèle n'a été notée dans le Groupe I contrairement à 3 cas (15.7%) dans le Groupe II ($P < 0.05$). Les paramètres du sperme ont été améliorés dans les 2 groupes après la chirurgie. L'amélioration moyenne de la concentration des spermatozoïdes était d'environ 32.5 millions de spermatozoïdes/ml dans le Groupe I et de 25 millions de spermatozoïdes/ml dans le Groupe II ($p > 0.05$). L'augmentation moyenne du nombre des spermatozoïdes était d'environ 96 millions de spermatozoïdes dans le Groupe I et de 92 millions de spermatozoïdes dans le Groupe II ($p > 0.05$). L'amélioration moyenne de la mobilité des spermatozoïdes était de 16.5% dans le Groupe I et de 14.1% dans le Groupe II ($p < 0.05$). La baisse moyenne du pourcentage de formes anormales de spermatozoïdes était d'environ 20% dans le Groupe I et de 5.5% dans le Groupe II ($p < 0.05$). La qualité de la mobilité était plus améliorée après ligature de varice par laparoscopie comparée à la chirurgie ouverte. **Conclusion:** La laparoscopie est une excellente option pour la varicocélectomie chez les patients obèses. Comparée à la chirurgie ouverte la laparoscopie présente une moindre morbidité et une plus courte convalescence. Un avantage particulier de la laparoscopie par rapport à la chirurgie conventionnelle est la possibilité de faire la ligature bilatérale à travers les mêmes 3 orifices d'abord. Dans cette étude l'amélioration de certains paramètres du sperme était significativement plus marquée après ligature des varicocèles par laparoscopie. Cela pourrait s'expliquer par une meilleure visibilité des varices par laparoscopie.

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