
ORIGINAL ARTICLES

ANTEGRADE SCROTAL SCLEROTHERAPY VERSUS INGUINAL MICROSURGICAL VARICOCELECTOMY IN THE TREATMENT OF VARICOCELE – A PROSPECTIVE, RANDOMIZED, PARALLEL GROUP STUDY

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Objective To evaluate the efficacy, safety and cost-effectiveness of antegrade scrotal sclerotherapy (ASS) compared to inguinal microsurgical varicocelectomy (IMV) for the treatment of varicocele of the testis.

Patients and Methods Male patients above 13 years of age with grade 2 to 3 varicocele, who were either symptomatic or presented with an abnormal semen analysis, were included in the study. The patients were randomized in a ratio of 1:1 between ASS or IMV. ASS was performed using sodium tetradecyl sulphate (Fibro-vein®) as sclerosing agent in a 1% and 3% mixture. IMV was performed using an inguinal approach and microsurgery loupes during spermatic cord dissection to identify and preserve the testicular artery and lymphatics. Color doppler ultrasound was used to measure testicular volume and pampiniform vein diameter before treatment and at 6 and 12 month follow-up visits. Semen analysis was obtained at the same time intervals. The efficacy parameters included serum follicle stimulating hormone (FSH), luteinizing hormone (LH), semen analysis, pregnancy rate of partners and estimation of costs involved.

Results Between April 2000 and December 2003, 25 patients were included in the study. ASS was performed on 12 patients (6 bilateral procedures) and IMV on 13 patients (2 bilateral). Obliteration of the clinically

detectable varicocele was achieved in 10/12 patients in the ASS and in 11/13 in the IMV group (89% and 87% success rate, respectively). ASS was superior to IMV with regard to costs, average theatre time, hospitalization and postoperative recovery. Both procedures had a one year pregnancy rate of 50%. The mean sperm count and mean sperm morphology improved significantly from baseline to 12 months in both groups. However, there were no statistically significant differences between the two methods with regard to semen analysis improvement, testicular volume or biochemical data (LH, FSH, testosterone). Serum FSH decreased in those who had successful treatment of their varicocele, but not in those with recurrence, although the difference was not statistically significant ($p=0.09$), probably due to the small patient numbers.

Conclusion ASS is a minimally invasive treatment for varicocele, which is feasible as an out-patient procedure in adolescents and adults. It can save costs, theatre time, hospitalization and time lost from work. ASS and IMV appear to be equally successful in terms of varicocele recurrence, pregnancy rate and semen analysis improvement.

Keywords varicocele, sclerotherapy, microsurgical varicocelectomy, male infertility

INTRODUCTION

A varicocele can be defined as an abnormal dilation and tortuosity of the internal spermatic veins and pampiniform plexus. The concept of retrograde blood flow through the internal spermatic vein is crucial in the pathogenesis of impaired spermatogenesis caused by a varicocele. Varicoceles are rarely diagnosed before puberty, with an incidence of approximately 6% in pediatric patients at age 10 years. The incidence of varicocele increases throughout puberty, and at age 13 it reaches 15% - 20%, a rate similar to that reported in adults¹⁻³.

There is a clear association between varicocele, infertility and testicular growth arrest⁴. Varicocele is present in 19% - 41% of men with primary infertility and 45% - 81% of men with secondary infertility⁵, and it is therefore the most common correctable cause of infertility in men. Surgical correction of varicocele is associated with significant improvement in sperm density, motility and morphology using the Kruger strict criteria⁶.

Gorelick and Goldstein suggest that varicocele causes a progressive decline in fertility and that prior fertility in men with varicocele does not predict resistance to varicocele induced impairment in the future - so called "secondary infertility"³. Various mechanisms have been suggested to account for the testicular dysfunction associated with varicoceles. Increased testicular and scrotal temperature⁷, retrograde flow of toxic metabolites from the adrenal and kidney in the spermatic vein⁸, venous stasis with germinal epithelial hypoxia and androgen deprivation are all mechanisms by which varicoceles can induce apoptotic pathways or be associated with testicular dysfunction caused by reactive oxygen species⁹.

Malondialdehyde (MDA) was identified as a measure of lipid peroxidation and increasing levels of MDA are associated with higher grades of varicocele⁹. Recently it was suggested that subnormal levels of sFas may be responsible for increased apoptosis induced by the Fas system, resulting in impaired spermatogenesis in patients with varicocele¹⁰. The Fas system is a widely recognized apoptosis signal transduction pathway in which a ligand receptor interaction triggers the cell death pathway. This system has been recognized as a key physiological regulator of apoptosis of testicular germ cells.

The ideal method of varicocele treatment is still a matter of controversy. Three open surgical approaches are currently used: subinguinal approach (Marmar), inguinal approach (Ivanissevich) and retroperitoneal (Palomo). In recent years microsurgical and laparoscopic methods have also been used. Percutaneous retrograde sclerotherapy or embolization as well as antegrade scrotal sclerotherapy are also used today in the treatment of varicocele^{11,12}.

Each technique has its own advantages and disadvantages, and conflicting results have been obtained from different studies. Comparative studies evaluating the results of different techniques of treatment of varicocele are scant in the literature.

Antegrade scrotal sclerotherapy (ASS) was developed by Tauber and Johnsen^{12,13} in the late 1980's and was used with great success in Europe and especially Germany, where it probably remains the treatment of choice today. Various studies were recently published in the literature, which confirmed that Tauber's antegrade scrotal sclerotherapy is a safe and effective treatment of varicocele in adults, adolescents and children^{11, 14-17}.

Inguinal microsurgical varicocelectomy (IMV), as an artery and lymphatic sparing technique, was described by Goldstein et al. in 1992¹⁸. It was also confirmed as a procedure with an extremely high success and minimal complication rate in adolescents¹⁹. Antegrade scrotal sclerotherapy was compared in the literature to other techniques in both retrospective²⁰ and prospective²¹ studies, but to our knowledge this is the first prospective randomized study comparing antegrade scrotal sclerotherapy to microsurgical inguinal varicocelectomy.

PATIENTS AND METHODS

The protocol for this prospective study was approved by the Ethical Committee of the Faculty of Health Sciences, University of Stellenbosch at Tygerberg Hospital. Between April 2000 and December 2003, 25 patients were included with a total of 33 varicoceles* that were grade 2 or 3 according to the Dubin and Amelar classification²².

The diagnosis was based on physical examination and scrotal color Doppler ultrasound

findings. The inclusion criteria were male patients aged 13 years or older, symptomatic varicocele (grade 2/3), asymptomatic patients with an abnormal semen analysis^{23,24} and adolescents with either testicular growth arrest or bilateral varicocele²³. Testicular growth arrest was defined as a more than 2 ml size variation as measured by ultrasound between left and right testis²³⁻²⁵. Other inclusion criteria were previous treatment failure at least 6 months after previous varicocele treatment, and a large varicocele associated with a change in testicular consistency²⁶.

The patients were randomized to antegrade scrotal sclerotherapy (ASS) or inguinal microsurgical varicocelectomy (IMV) in a 1:1 ratio. All the patients were closely monitored with clinical and ultrasound examination at 3, 6 and 12 months after surgery. Semen analysis, serum testosterone, luteinizing hormone (LH) and follicle stimulating hormone (FSH) were obtained before treatment and at 6 and 12 months after surgery. Semen analysis was performed according to the WHO criteria. All blood tests were performed between 11h00 and 12h00 to eliminate variation due to the normal physiological rhythm. Semen analysis was carried out in patients with subfertility or infertility or in those patients 18 years or older or who were sexually active^{27,28}.

The method we used to determine the sick leave after surgery was different from other studies. At one month follow-up the patient was asked if the period of sick leave had been sufficient and, if not, what he would have recommended.

Antegrade Scrotal Sclerotherapy (ASS)

The surgical technique used was the one described by Tauber et al.^{12,13}. The patients were placed supine in a slight Trendelenburg position. All cases were done under local anesthesia in a day surgery unit. After one early case of severe bradycardia caused by traction on the spermatic cord, all patients received 0.2 mg glycopyrrolate (Robinul®) intravenously as pre-medication just before the procedure.

The operative field was disinfected and the proximal third of the scrotum shaved. Peripheral venous access was obtained without sedation. Deep infiltration anesthesia was induced at the level of the penile root by injecting a mixture of 10 ml of 1% lignocaine hydrochloride and bupivacaine (50 mg/10 ml) in a 1:1

ratio, into the spermatic cord and surrounding area, and another 1 ml into the area of the planned incision.

The spermatic cord was delivered through a 1-2 cm scrotal neck incision, one finger breadth below the root of the penis, and looped. A straight, dilated vein of the pampiniform plexus was selected from among those merging into the spermatic vein. These veins can be easily recognized by the dark yellow fat surrounding them. The vein was exposed and distally ligated. After incision, a 24 gauge thin walled cannula was introduced into the vein in an antegrade fashion. While advancing the cannula a few ml of physiological saline was injected. The cannula was secured with a single ligature and antegrade phlebography was undertaken by infusing 4 to 5 ml of contrast medium, allowing an assessment of the correct position of the cannula in the pampiniform vein.

X-ray exposure during fluoroscopy was supragenadal, with a total duration of 3-5 seconds. The sclerosing agent used was 3 ml of a 2% solution of sodium tetradecyl sulphate (STD) (Fibro-vein®, STD Pharmaceuticals, Fields Yard, Plough Lane, Hereford, England). We used an air block technique (1 ml of air, followed by 3 ml of the sclerosing agent). The patient was instructed to perform a Valsalva maneuver during injection. Only one injection was performed, the cannula was then removed and the vein ligated. The opened spermatic cord fascia was closed with a suture and the skin closed with 2 to 3 interrupted 3-zero catgut.

Inguinal Microsurgical Varicocelectomy (IMV)

The method initially described by Goldstein et al.¹⁸ in adults and later also by Minevich et al. in adolescents was used¹⁹. All patients received general anesthesia. The spermatic cord was approached through a 2 cm skin incision over the inguinal canal. The external oblique aponeurosis was opened and the ilio-inguinal and genital branch of the genito-femoral nerve identified. The spermatic cord was delivered. All identifiable external spermatic veins were ligated and divided.

The spermatic fascia was opened and spermatic cord dissection continued using the micro-surgical loupes. The vas deferens and accompanying vessels as well as the testicular artery were identified and were maintained out of the field of dissection. All identified lymphat-

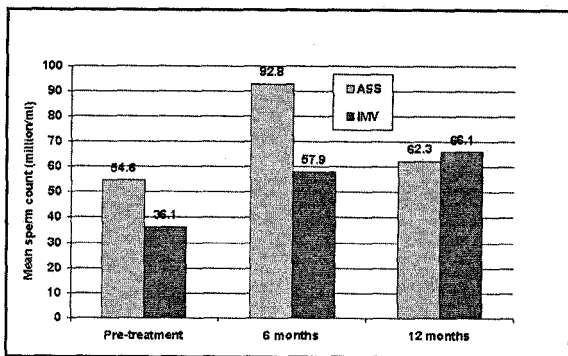


Fig. 1: Mean sperm count before treatment and at 6 and 12 months follow-up

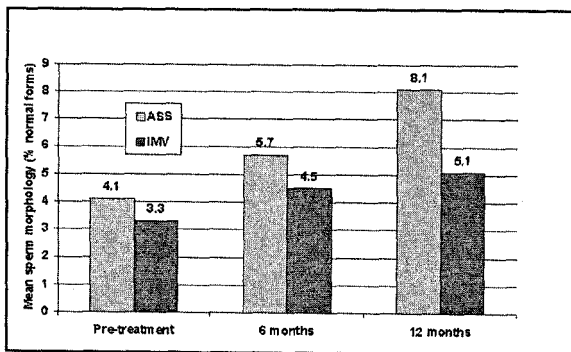


Fig. 2: Mean sperm morphology (according to Kruger's strict criteria) before treatment and at 6 and 12 months follow-up.

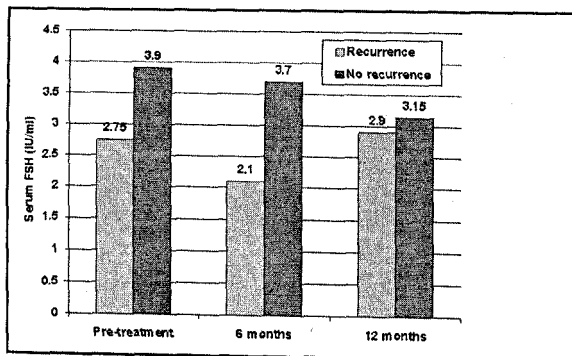


Fig. 3: Mean serum FSH levels in patients with and without recurrence of varicocele after treatment (data from ASS and IMV groups combined)

ics were preserved. All veins within the spermatic cord except the vasal veins were doubly ligated with 4-zero silk ties and divided. During the dissection the number of external spermatic veins ligated was recorded. The vasal veins were never ligated even if they were larger than 2 mm in diameter, as recently sug-

gested by Hopps et al.²⁹. Heine C surgical loupes (340 mm) with 2.3 × power magnification were used by the surgeon and the assistant.

After completion of the procedure the spermatic cord was returned and the external oblique aponeurosis sutured with continuous polyglycolic acid (Vicryl®) 1-zero, Scarpa's fascia was closed with interrupted Vicryl 3-zero, and the skin with subcutaneous monofilament polyglyconate (Maxon®) 4-zero.

Statistical analysis

The significance of postoperative seminal parameter changes, biochemical changes, duration of surgery and postoperative recovery period were analyzed using the Repeated Measures Analysis of Variance (ANOVA) and One Way Analysis test.

RESULTS

A total of 12 patients (18 varicoceles) underwent percutaneous sclero-embolization. Fourteen varicoceles were grade 3 and four grade 2. There were 6 unilateral and 6 bilateral varicoceles. In 6 patients (50%) the treatment was indicated because of infertility and low sperm quality, in 2 adolescents (17%) for co-existing hypotrophy of the ipsilateral testis with severe grade of varicocele and in 4 adults (33%) because of a symptomatic varicocele.

There were 13 patients in the IMV group (15 varicoceles) which consisted of 14 grade 3 and one grade 2 varicocele(s); 11 were unilateral and only 2 bilateral. In 8 (62%) infertility was the indication for surgery, in 3 (23%) because of symptoms and 2 (15%) patients had hypotrophy of the ipsilateral testis.

No patient required sedation or general anesthesia during ASS, the mean (range) duration of which was 37.8 (22-90) min. All patients in the IMV group received general anesthesia and the mean (range) duration of the procedure in this group was 55.5 (30-90) min. The difference in the mean duration of surgery between the two methods was statistically significant ($p < 0.01$).

Only one intra-operative complication was recorded. The patient developed severe bradycardia due to traction on the spermatic cord during ASS. After this complication, 0.2 mg

Table 1: Cost Comparison between Antegrade Scrotal Sclerotherapy and Inguinal Microsurgical Varicocelelectomy

	Cost (Euro)		Cost (South African Rand)	
	ASS	IMV	ASS	IMV
Theatre time	€ 199.17	€ 244.27	R 1 563.50	R 1 917.50
Hospitalization	€ 40.42	€ 40.42	R 317.30	R 317.30
Administration and Dispensing fees	€ 6.61	€ 6.61	R 51.90	R 51.90
Radiological screening	€ 21.34	€ 0.00	R 167.50	
Anesthetic gas	€ 0.00	€ 22.97		R 180.32
Theatre disposables	€ 86.00	€ 144.75	R 675.10	R 1 136.30
Ward disposables	€ 0.48	€ 10.87	R 3.75	R 85.35
Radiographer's fee	€ 14.52	€ 0.00	R 114.00	
Contrast medium	€ 17.79	€ 0.00	R 139.64	
Anesthetist's fee	€ 0.00	€ 74.78		R 587.02
Subtotal	€ 386.33	€ 544.67	R 3 032.69	R 4 275.69
Urologist's fee	€ 93.04	€ 32.61	R 730.34	R 256.00
Assistant's fee	€ 0.00	€ 24.31		R 190.80
Total	€ 479.37	€ 601.59	R 3 763.03	R 4 722.49

glycopyrrolate (Robinul®) as premedication was instituted and the complication did not recur. No patient showed any allergy to the contrast medium or to the sclerosing agent. In the ASS group, one patient (8%) had a complication after treatment. He developed a cord hematoma, which subsided with conservative treatment. No complications were recorded in the IMV group.

All patients who underwent ASS were discharged less than 2 hours after the procedure. The patients who had IMV performed had to recover from general anesthesia and were discharged between 4 and 6 hours post surgery. Two patients, both with bilateral varicocele, were retained in the hospital the night after IMV was performed. A mean time of going back to work of 6.9 days was noted in the ASS group and 12.6 days in the IMV group ($p < 0.01$).

A detailed cost analysis for both procedures performed by one urologist in the same private hospital showed that ASS was less expensive than IMV, even though the statutory (fixed) Urologist's fee for ASS was higher than for IMV (Table 1).

No testicular atrophy or postoperative hydrocele was recorded. Recurrence was defined as clearly visible or palpable varicocele (grade 2 or 3) identified at 3, 6 and 12 months and confirmed by ultrasound. In the ASS group a persistent varicocele was noted in 2 patients 6 months after surgery. Out of a total of 18 varicoceles, 16 were successfully treated (89% success rate). Two varicoceles recurred in the IMV group (87% success rate). In all cases of recurrence the varicoceles were smaller than before surgical treatment – the grading changed to grade 2.

In the ASS group out of the 6 patients who had varicocelelectomy performed for infertility, 3 partners became pregnant within a year after surgery (50% pregnancy rate). Nine patients had sperm samples analysed at 6 months and 12 months after surgery. In the IMV group 8 patients had infertility as main complaint, and 4 of their partners became pregnant within one year (50% pregnancy rate). Eleven patients came for sperm analysis at 6 and 12 months after surgery. There was no statistically significant difference between the two methods with regard to mean sperm count improvement ($p = 0.44$) (Fig.1). However, the mean sperm

count improvement over time for both methods (combined data) was statistically significant ($p=0.03$).

In both groups the mean sperm morphology (using Kruger's strict criteria) increased significantly from baseline to 12 months ($p<0.0004$), but there was no statistically significant difference between the two treatment methods ($p=0.13$), although there appeared to be a tendency for the ASS group to have better sperm morphology (Fig. 2).

When evaluating the serum FSH response after treatment, the three adolescents were separated from the adults. In adolescents it was confirmed by Fisch et al. that baseline FSH levels were higher after surgery than before³⁰. The role of monitoring FSH after treatment in adults is poorly defined, but considering the physiological role of FSH, it can be expected to decrease after successful treatment of varicocele. In the four patients who had varicocele recurrence, the FSH did not change significantly, whereas in the group of patients who had successful treatment of the varicocele, the FSH decreased, with a trend towards significance ($p=0.09$) (Fig. 3).

The serum LH and testosterone did not show any significant changes after surgery. No significant change in testis volume was recorded in the adult population, but all three adolescents had an increase in testis volume at 12 months post treatment.

DISCUSSION

Varicoceles have been associated with testicular growth arrest and infertility in adults, and they have deleterious effects on sperm density, morphology and motility. Currently it is accepted that varicocelectomy is a cost-effective treatment for male infertility³¹, and there is a general consensus to treat varicocele in adolescents to prevent irreversible alterations.

In this randomized, prospective study we compared the efficacy and safety of two modern and well-established methods (ASS and IMV). The success of varicocele ligation depends on the ability to decompress the varicocele completely with minimal injury to the arteries, lymphatics, and vas deferens. Postoperative varicocele persistence or recurrence and hydrocele formation are the most commonly reported and most significant complications of

varicocele surgery. The reported incidence of hydrocele formation after standard Palomo operation is 3% to 25%³². The complete absence of any postoperative hydroceles or testicular atrophy was previously described as the greatest advantage of the microscopic technique¹⁸. By using the microsurgical technique we were better able to visualize and preserve the lymphatic vessels and the testicular artery, thereby eliminating the occurrence of hydrocele. Postoperative hydroceles are not a known complication after ASS¹², and in our study this was confirmed.

Tauber and Johnsen reported on 291 patients treated for 317 varicoceles with ASS¹². In 91% of the 285 cases with a minimum follow-up of 12 months there was no evidence of varicocele recurrence. A literature review by Ficarra et al. noted a persistence rate of 5%-13% using ASS¹⁴. Our success rate of 89% correlates with this figure.

Previously reported persistence rates for IMV range from 1-2% using the microscope¹⁹. However, more recently Greenfield et al. reported an approximately 90% success rate after microscopic varicocelectomy³³, and stated that use of the microscope does not guarantee success. Our experience with IMV and operating loupes also supports this opinion, with our success rate of 87% for this technique.

Several authors have noted improvements in semen quality after varicocele ligation in previously infertile patients^{6,31}. We could not demonstrate a significant difference between ASS and IMV in improving semen quality – both being very successful. In our study even the pregnancy rate after one year follow-up was exactly the same for the two procedures, namely 50%. This figure correlates with the study done by Tauber and Johnsen¹² who documented a 42% pregnancy rate by using the ASS technique.

In this study the patient's opinion was asked to determine the recovery time after surgery. The definition of sick leave used in this study was the time needed to resume normal working activities. This was longer than expected and reported in other studies^{34,35}, but it may be an indication that we as doctors underestimate the time needed for recovery after surgery.

An interesting and novel idea would be to use the serum FSH at 6 and 12 months after

varicocelectomy to predict the improvement in sperm quality. This easy investigation could possibly eliminate the need for repeat sperm analysis after treatment in infertile patients. Our data showed a different pattern in post-treatment FSH levels for patients who had successful varicocelectomy compared to patients who had persistence or recurrence of varicocele. Unfortunately our study population was too small for this finding to be statistically significant, but the observation does warrant further study.

Recently Tanaka et al. concluded that serum luteinizing hormone levels correlated positively with CPP32 staining³⁶. CPP32 is caspase-3, a protease belonging to the caspase family, known to induce apoptosis when over-expressed in mammalian cells. The reduced expression of CPP32 participates in regulating apoptosis in the testes of infertile men with varicocele. We were not able to demonstrate any significant change in serum LH after treatment of varicocele for infertility.

The only intraoperative complication we experienced during ASS was severe bradycardia secondary to vagal stimulation induced by spermatic cord traction. Ficarra et al. described giving 0.5 mg atropine and 10 mg diazepam through IM injection before surgery¹⁴. We prefer to have venous access during ASS, in case of an allergic reaction to the contrast or sclerosing agent. We now routinely give glycopyrrolate 0.2 mg intravenously 5 minutes before surgery, and have never encountered the need to use a sedative during the procedure.

In this study an increase in testicular volume after varicocelectomy was not apparent. This can be explained by our older population of patients, because "catch-up" growth is a phenomenon that has been observed in 70%-80% of adolescents following varicocele ligation³³. We observed a tendency towards catch-up growth in our adolescent patients, but it was not statistically significant.

In conclusion, the management of varicoceles remains controversial. Urologists are faced with a variety of treatment options. Very few randomized, prospective studies exist to guide the surgeon in his decision-making about the appropriate method. The two techniques we compared, namely ASS and IMV, appear to be equally successful in terms of varicocele recurrence, pregnancy rate and semen analysis improvement. However, ASS is a minimally

invasive technique, which is feasible as an outpatient procedure in adults and adolescents. It can save costs, theatre time, hospitalization and time lost from work. We believe that, in the future, serum FSH analysis after treatment may decrease the need for repeated semen analysis in the follow-up of these patients.

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RESUME

La sclérothérapie ante grade de varicocèle versus varicocelectomie microchirurgicale par voie inguinale dans le traitement de la varicocèle - étude prospective randomisée parallèle

Objectifs : Evaluer l'efficacité, la sécurité et la rentabilité de la sclérothérapie ante grade de varicocèle (ASS) comparée à la varicocelectomie microchirurgicale par voie inguinale (IMV) dans le traitement de la varicocèle. **Patients et méthodes** : Des patients de sexe masculin d'âge de plus de 13 ans avec une varicocèle de grade 2 à 3 qui étaient ou symptomatiques ou présentant une anomalie à l'analyse du sperme ont été inclus dans l'étude. Les patients ont été randomisés dans un ratio de 1:1 entre ASS

ou IMV. L'ASS a été réalisée utilisant le sulfate de tétradécyl de sodium (Fibro-vein®) comme agent du sclérosant dans une dilution à 1% et 3%. IMV a été réalisée utilisant une approche inguinale et loupes de microchirurgie pendant la dissection du cordon spermatique identifiant et conservant ainsi l'artère testiculaire et les lymphatiques. L'échographie doppler couleur a été utilisée pour mesurer le volume testiculaire et le diamètre des veines du plexus pampiniforme avant traitement et à 6 et 12 mois. De même pour l'analyse de sperme. Les paramètres de l'efficacité ont inclus les taux sériques de l'hormone stimulante folliculaire (FSH), l'hormone de luteinisation (LH), analyse du sperme, le taux de grossesse de partenaires et estimation du coût impliqué. **Résultats** : Entre avril 2000 et décembre 2003, 25 patients ont été inclus dans l'étude. L'ASS a été réalisée chez 12 patients (dont 6 bilatérales) et l'IMV sur 13 patients (2 bilatéral). L'oblitération de varicocèle détectable à l'examen clinique a été obtenue chez 10/12 patients dans l' ASS et en 11/13 dans l'IMV (respectivement 89% et 87% de taux de succès). L'ASS était supérieure à IMV quant au coût, la durée opératoire moyenne, l'hospitalisation et la récupération postopératoire. Les deux procédures avaient un taux de grossesse de 50% dans l'année. Le compte du sperme moyen et la morphologie du sperme moyenne étaient améliorés considérablement à 12 mois dans les deux groupes. Cependant, il n'y avait pas de différences statistiquement considérables entre les deux méthodes quant à l'amélioration de l'analyse du sperme, volume testiculaire ou données biochimiques (LH, FSH, testostérone). La FSH a diminué chez ceux qui avaient un traitement efficace de leur varicocèle, mais pas chez ceux avec récurrence, bien que la différence ne fût pas statistiquement considérable ($p=0.09$), probablement dû aux petits nombres de patients. **Conclusion**: L'ASS est un traitement imperceptiblement invasif de la varicocèle qui est faisable comme acte en consultation externe chez les adolescents et les adultes. Il est économique sur le plan coûts, temps opératoire, hospitalisation et temps d'invalidité. L'ASS et l'IMV paraissent être également efficaces quant à la récurrence de la varicocèle, taux de la grossesse et amélioration de l'analyse du sperme.

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