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Remote Outcomes of Sclerotherapy with Ethanol in Hydrocele Patients

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Abstract--- Introduction*. Conventional methods of treating hydrocele are rather traumatic and seem unsatisfying to both doctors and patients; therefore, their improvement is is needed.*

Objective of this study *is to evaluate the efficiency and safety of sclerotherapy of hydrocele with 96% ethanol.*

Patients*: 117 patients aged from 35 to 89, with hydrocele volume over 100 ml, were divided into three groups: 34 patients who received sclerotherapy by the studied method; 25 patients who received conventional sclerotherapy; 58 patients who received a widely adopted surgery. The improved sclerotherapy included 30–40 min exposure to ethanol, subsequent evacuation of ethanol from the scrotum, and repeated injection of 5–10 ml of ethanol without evacuation.*

Results*: In Group I the first sclerotherapy cured 97.1% of patients; in Group II, 72%. During two months after the therapy, complications were observed in 14.5%, 16% and 62.2% of patients, respectively. In Group I, 24 patients assessed tolerability as excellent, 10 patients as good. In Group II only 13 patients assessed tolerability as excellent, while 8 patients marked it poor. In Group III, 20 patients assessed tolerability as excellent and 16 patients as poor. The spermatogenesis rate was 8.7±0.5 before and 8.6±04 after the sclerotherapy (Johnsen scale modified by De Kretser and Holstein). The testicle volume on the hydrocele side was 20.9±1.5 cm^3 after sclerotherapy, against 25.2±2.2 cm^3 prior to it. The linear blood flow velocity in parenchyma arteries was 0.104+0.020 m/s before and 0.122+0.024 m/s after the sclerotherapy. The average resistivity index in parenchyma arteries was 0.81±0.05 m/s before and 0.74±0.06 m/s after the sclerotherapy. These average values were found to be statistically reliable ($p<0.05$). No reliable change in the spermogram was revealed 6 months after the treatment.*

Conclusions*. The improved sclerotherapy with 96% ethanol minimized the hydrocele relapse and reduced early postoperative complications. This method showed no adverse effect upon the testicle tissue; on the contrary, it conduced to better blood supply and lymph efflux from the parenchyma, which can be confirmed by the examination results.*

Keywords*--- Hydrocele, Sclerotherapy, Ethanol, Spermatogenesis.*

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I. INTRODUCTION

Hydrocele is normally found in 1.5–3.9% of male patients of both reproductive and elderly age [Tiktinskiy et al. 2010].

Although it seems harmlessness, the disease often manifests itself as a cosmetic defect or a movement, urination and sexual discomfort; occasionally it may cause pain, which impairs quality of life in hydrocele patients [Tiktinskiy et al. 2010, Dagrosa et al. 2015]. It was proved that hydrocele has a negative effect upon testicle secretion, predisposes to testicle carcinomas, and sometimes leads to testicular rupture, by disturbing testicle blood supply and lymph efflux [Dovgilev 2010, Mihmanli et al. 2004, Yamamichi et al. 2015]. That said, there is still a need for a more efficient therapy against hydrocele.

Unsatisfactory outcomes of conventional approaches to hydrocele surgery prompted further development of scrotoscopy and video endoscopy and the use of laser and radio wave scalpels [Grinev et al. 2005, Dovgilev 2010, Yang et al. 2015, Yin et al. 2015, Peng et al. 2015, Sim 2015]. One of minimally invasive methods is sclerotherapy because, as the previous work in this field suggests, injections of a sclerosing substance are largely safe [Malysheva et al. 2005, Shan et al. 2011]. Among sclerosing agents, 96% ethanol remains understudied.

There is evidence [Malysheva et al. 2005, Shan et al. 2011] that the incidence of good outcomes can range from 61 to 95%. Comparative analysis showed that, despite fewer complications, less post-operative pain and a more attractive price, aspiration and sclerotherapy are insufficiently satisfactory to both patients and doctors. The main disadvantages are repeated sclerotherapy sessions and a rather high rate of relapse, particularly in patients with very large hydroceles, which made such methods less valuable. In clinical practice, repeated sclerotherapy sessions are needed for about 20–30% of patients, and it extends treatment and recovery periods.

Thus, the conventional operations on hydrocele are rather traumatic for patients, and the outcomes of aspiration and sclerotherapy seem unsatisfying. Therefore, hydrocele treatment methods require further improvement.

II. PATIENTS, MATERIALS AND METHODS

This study was based on the results of medical examinations and treatment of 117 hydrocele patients from 2008 through 2015. All the patients were divided into three groups:

Group I – 34 patients with hydrocele volume of over 100 ml who received sclerotherapy by 96% ethanol by the new improved method. The improved sclerotherapy method implied spermatic cord blocking by lidocaine, ultrasonic-controlled scrotum puncture by a trocar, insertion of the Foli F8-10 catheter, evacuation of the contents and injecting ethanol in the amount of 40–100 ml, depending on the size and volume of hydrocele, exposition for 30–40 min, evacuation of ethanol from the scrotum and repeated injection in the amount of 5–10 ml, no evacuation.

Group II – 25 patients with hydrocele volume of over 100 ml who had conventional sclerotherapy.

Group III – 58 patients with hydrocele volume of over 100 ml operated by conventional methods (standard operations: Winkelmann's technique, von Bergman's technique).

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Patients' age varied from 35 to 89 years old. For the sake of patients' safety, the ethanol sclerotherapy was delivered only to patients of 40 years old and older.

Hydrocele was diagnosed proceeding from patient's complaints, case history, objective status and the results of special examination methods: diaphanoscopy, ultrasonography of the scrotum organs with Doppler examination, and examination of the hydrocele content.

In 12 patients of reproductive age, the hormonal state, the spermogram and the testicular tissue morphology were examined before the improved sclerotherapy and 4–6 months after it. The morphology of testicular tissue and tunics was examined prior to and 4–6 months after injecting ethanol in the bioptic samples of 12 voluntary patients (48 micro slides). The samples were obtained by the BARD MAGNUM bioptic gun (USA) using a biopsy needle, gauge 14G, 16 cm long. The biopic material was sampled as 2 pieces from both testicular tissue and testicular tunic; the sampling was ultrasound-controlled. The spermatogenetic status was evaluated using a median scale based on De Kretser and Holstein's data, as cited by Nikitin (2015).

The cause of hydrocele was a former varicocele surgery in 14 patients (11.9%), scrotum injury in 20 patients (17.1%), a history of epididymo-orchitis in 22 patients (18.8%), former scrotum or groin surgery in 16 patients (13.7%), and unknown (idiopathic) cause in 45 patients (38.5%).

The indications for surgery were cosmetic defects in 10 patients (8.5%), discomfort and a heavy feeling in the scrotum in 24 patients (20.5%), scrotum and testicular pains with radiation along the spermatic cord in 28 patients (23.9%), discomfort during sex in 23 patients (19.6%), combined reasons in 32 patients (27.7%).

The entry criteria for examination and treatment were: the age over 35, a hydrocele of over 100 ml, no signs of testicle malignancy, no signs of haematocele and epididymitis, no history of mental problems, homogeneous echo morphology of the hydrocele, and patient's informed consent. All patients signed informed consent forms.

Postoperatively, all the patients were followed-up for 2 years. The remote outcomes of the treatment were assessed in the patients after their discharge from hospital in 2–24 months. The results were evaluated on the basis of questionnaires, personal interviews, physical examination by touch, ultrasonography of the scrotum organs with Doppler examination.

III. RESULTS

The average volume of evacuated liquid in Group I was 397.3540,47 ml; in Group II, 346,7228,87 ml; and in Group III, 414,0050,53 ml.

The morphological analysis of the testicular tissues prior to the operation and 4–6 months after the sclerotherapy revealed the unchanged spermatogenic capacity in all 12 patients at all stages. However, the examination of testicular tunics confirmed the presence of inflammatory-infiltrative changes prior to and 20 days after administering the sclerotherapy. However, no such changes were found 3–6 months after the treatment.

In all fragments of the testicular tunic prior to the sclerotherapy, the connective tissue had sings of pronounced oedema and dissociation. There were revealed a significant number of vasodilated plethoric blood vessels, local

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haemorrhaging, unapparent local lymphoid inflammatory infiltration admixed with individual white cells (Fig. 1). Very similar changes were observed in many fragments of the testicular tunic 20 days after the sclerotherapy, which is linked to the sterile inflammatory reaction.

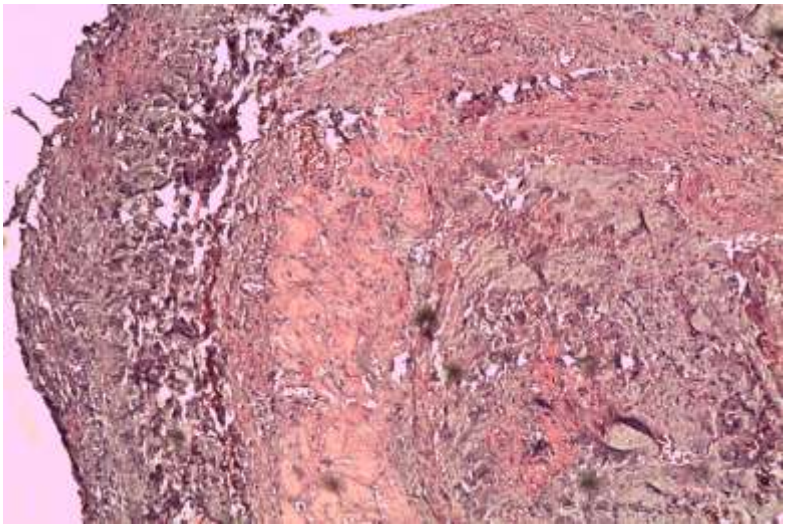

Figure 1: Testicular tunic morphology prior to the sclerotherapy; swelling and dissociation of the connective tissue; a large number of extended plethoric blood vessels with local haemorrhages (coloured by haematoxylin-eosin, zoom x10)

Further, sclerosis with a mild vascular pattern and no signs of oedema was observed in all fragments of testicular tunics 4–6 months after the sclerotherapy (Fig. 21, 26, 27). We are of opinion that the revealed pathomorphological changes subsequently lead to more developed sclerosis and result in a significant reduction in the liquid filtration.

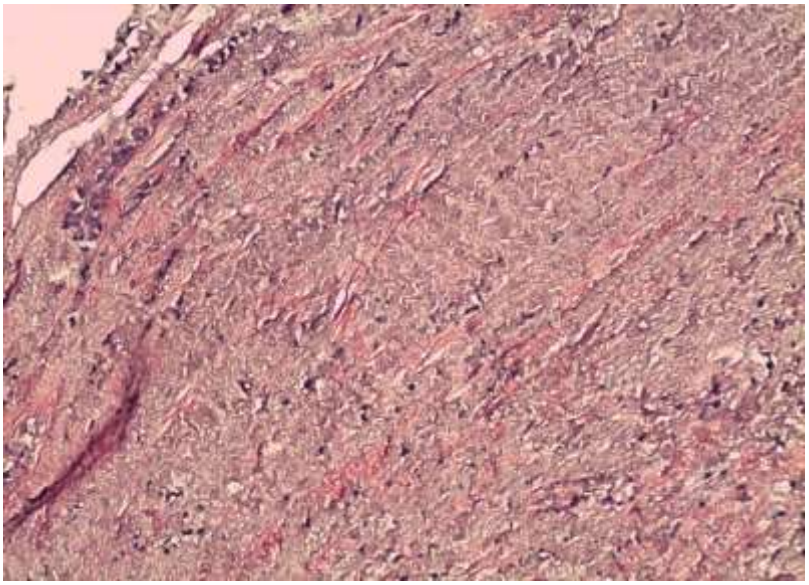

Figure 2: Testicular tunic morphology 4 months after the sclerotherapy; sclerosis with no oedema; a mild vascular pattern

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Prior to the sclerotherapy normal spermatogenesis was revealed in 8 out of 12 patients, and hyper spermatogenesis in 4 patients.

In the patients with normal spermatogenesis, the bioptic testicular samples showed tubules with a normal amount of elongated spermatids and all stages of spermatogenesis. In the patients with impaired spermatogenesis prior to the sclerotherapy, we revealed desquamated seminiferous epithelium containing spermatoblasts, primary and secondary spermatocytes, spermatids, and individual semens in the testicular tissue. The morphology of testicular tissue demonstrated a nearly similar picture of spermatogenesis in the tubules in 4 months after the sclerotherapy (Fig. 3, 4).

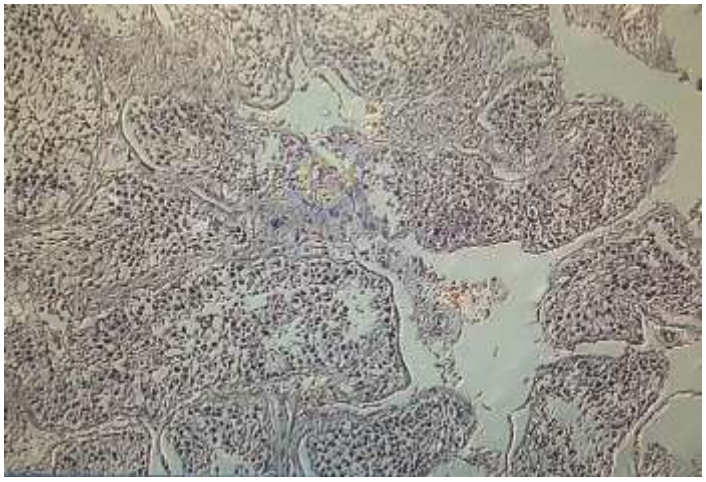

Figure 3; Testicular tunic morphology in 4 months after the sclerotherapy; all stages of normal spermatogenetic process and a normal amount of elongated spermatids can be observed in the testicular parenchyma.

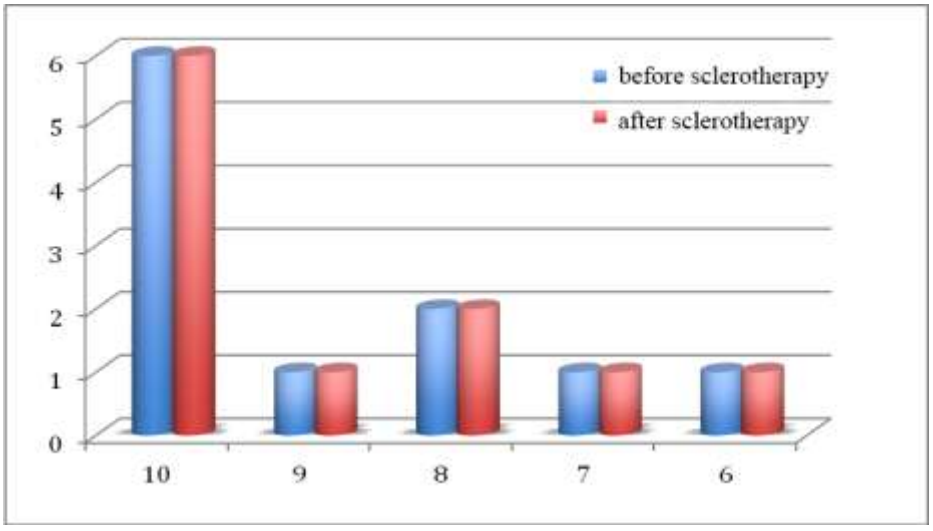

Figure 4: Evaluation of the spermatogenesis process by the spermatogeny scale before (blue) and after (red) the sclerotherapy

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According to the Johnsen scale modified by De Kretser and Holstein, the average rate of spermatogenesis was 8.7±0.5 before the therapy and 8.6±04 after the therapy. The assessment showed no reliable change prior to and after the sclerotherapy (Fig. 4).

In 2 months and later after patients' discharge from hospital, among postoperative complications there were observed wound infiltrate, relapses, and pain syndromes (Table 1). The postoperative infiltrate in the scrotum was revealed in 28 patients (48.3%) after the standard operations and none after the sclerotherapy. The spermatic cord infiltrate was observed in 5 patients (8.6%) after the standard operations and none after the sclerotherapy. A relapse of hydrocele was found in:

- 1 patient (2.1%) after the improved sclerotherapy (repeated sclerotherapy with positive outcome);
- 7 patients (31.8%) after the conventional sclerotherapy (three patients needed one repeated therapy session, and five patients needed three more such sessions; two patients were operated after the third therapy session);
- 2 patients (3.4%) after standard operations.

Table 1: Remote outcomes of different hydrocele treatments (2 months and later), where IST is the improved sclerotherapy, CST is the conventional sclerotherapy, SO is the standard operation, and * denotes $p<0.05$.

Complications	Treatment method					
	IST		CST		SO	
	Absol.	%	Absol.	%	Absol.	%
Postoperative scrotum infiltrate	-	-	-	-	28	48.3*
Semen tube infiltrate	-	-	-	-	5	8.6
Hydrocele relapse	1	2.9	7	28*	2	6.9
Pains and discomfort in the scrotum area	1	2.9	1	4.0	15	25.8*
TOTAL	2	5.8	8	32.0	50	86.2*

The time of infiltrate discussion depended on its location. The infiltrates in the spermatic cord dissolved significantly earlier and caused little discomfort to the patients. The infiltrates in the scrotum dissolved over the period of several months and were the cause of pain and discomfort in the patients.

As the questionnaire survey showed, after 12 months the postoperative infiltrate in the scrotum disappeared in 16 (27.6%) out of 28 (48.3%) patients who underwent standard operations; in 12 (20.7%) patients it remained. The infiltrate in the spermatic cord disappeared in all groups of patients. Pains and discomfort in the scrotum area after the standard operations remained in 10 (17.2%) out of 15 (25.7%) patients, while such discomfort persisted in 1 patient (4%) after the conventional sclerotherapy.

In Group I, 24 patients (70.6%) assessed tolerability of the improved sclerotherapy as very good; the rest (10 patients, 29.4%) reported it to be good. Tolerability of the conventional sclerotherapy was assessed as follows: 13 patients (52%) – excellent, 6 patients (24%) – good, 8 patients (32%) – poor. Tolerability of the standard operations was assessed as follows: 20 patients (34.5%) – excellent, 22 patients (37.9%) – good, while 16 patients (27.6%) – poor (Fig. 5).

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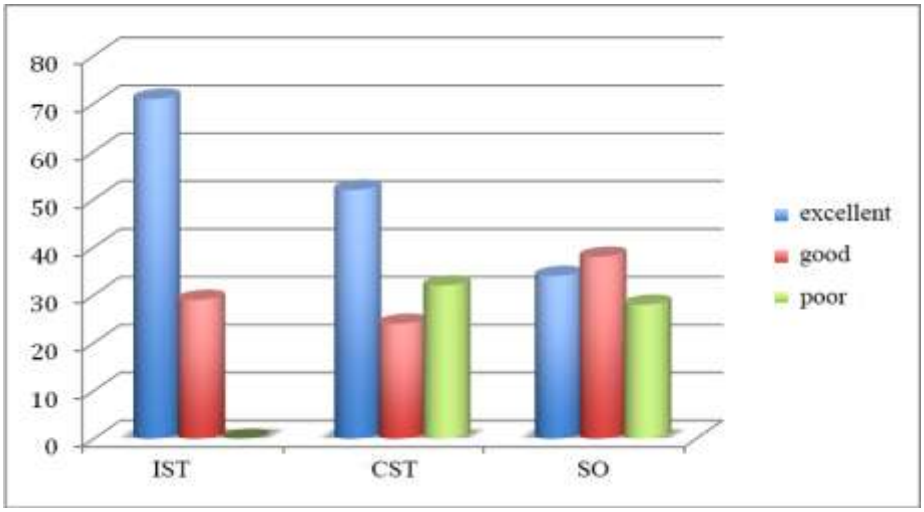

Figure 5: Treatment tolerability distribution by the group; here abbreviations are the same as for Table 1.

The cosmetic effects of the sclerotherapy were reported to be excellent by all the patients, whereas after the standard operations the distribution was as follows: 12 (21.9%) – excellent, 22 (37.9%) – good, 18 (31.03%) – satisfactory, 8 (13.8%) – poor.

Hence, the remote outcomes of hydrocele therapy depended on the technique employed. Good and satisfactory results in patients who received the improved sclerotherapy were significantly more frequent, while some patients who received the conventional sclerotherapy showed more unsatisfactory outcomes in connection with repeated therapy sessions.

The follow-up ultrasound examinations 6–12 months after the therapy confirmed that the total volume of testicles was 20.9±1.5 cm^3 on the hydrocele-affected side (prior to operation it was 25.2±2.2 cm^3) and 20.5±1.3 cm^3 on the healthy side (Fig. 6). This difference on the affected side prior to and after the sclerotherapy was found to be statistically reliable ($p<0.05$).

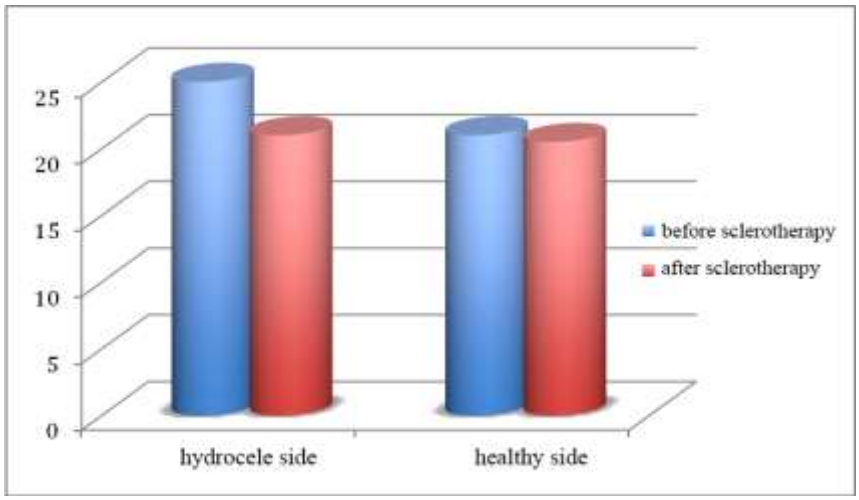

Figure 6: Testicle volume prior to and after the sclerotherapy

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The average linear blood flow velocity in parenchyma arteries (Table 2) in hydrocele patients was 0.104+0.020 m/s, before the operation and 0.122+0.024 m/s after the operation. The average resistivity index in parenchyma arteries was 0.81± 0.05 m/s before the operation and 0.74± 0.06 m/s after the operation. The average values of pulsatility index (PI) were 1.02± 0.46 and 9.04± 0.44, respectively.

Table 2: Arterial blood flow values in testicle parenchyma arteries in patients with hydrocele, pre/postoperatively, where LBV is the blood flow velocity, RI is the resistivity index, PI is the pulsatility index, and * denotes $p<0.05$.

Parenchymal arterie	Haemodynamics parameters (n=56)				
	LBV, cm (max)	LBV, cm (min)	LBV, cm (meduim)	RI	PI
Preoperatively	0.154 +0.026	0.062 +0.014	0.104 +0.020	0.81 ±0.05	1.02 ±0.46
Postoperatively	0.166 +0.020	0.068 +0.11	0.122*+0.024	0.74*±0.06	9.04 ± 0.44

Therefore, along with reduction in the testicle volume, it was observed that the haemodynamics on the hydrocele side changed if compared with the healthy side, which is linked to better lymph circulation both in the testicular vaginal tunic and in the parenchyma, smaller oedema and better blood flow.

No reliable hormonal changes in the blood serum were revealed preoperatively and 4–6 months after the sclerotherapy.

The average ejaculate volume in the patients remained nearly unchanged prior to and after the sclerotherapy (3.2±0.2 ml and 3.0±0.2 ml respectively). The sperm cell density was within the normal range (20.2±4.4 mln/ml), no reliable change was detected postoperatively (21.2±3.4 mln/ml). The sperm motility (a+b+c) was 55.2±2.2% prior to the sclerotherapy and 60.4±2 after the sclerotherapy. Abnormal sperm density reduction was detected in 1 patient (4%). These changes were mainly related to the motility and the pathological forms of sperm. This patient was administered an appropriate therapy, and the case follow-up showed that one year was enough to bring his spermogram back to normal.

To sum up, the findings confirm that the sclerotherapy brings no reliable change to the spermogram parameters.

IV. DISCUSSION

Hydrocele appears to be an urgent problem till the present day because of complications and lack of consensus among researchers which therapy or operation technique is best suited to each particular case [Manganiello et al. 2013, Kliesch 2014].

The conventional-technique upfront surgery through a cut in the scrotum (Winkelmann's, von Bergman's, Lord's) remains the most widely adopted method of curing hydrocele [Dovgilev 2010, Saber 2015]. However, the outcomes of such operations are frequent oedemas and scrotum infiltrations persisting for months after the surgery. Moreover, this type of surgery can be traumatic, causing such complications as haematomas, bleeding, scrotal oedema, wound abscess, lymphostasis, postoperative epididymitis and orchitis; an occasional hydrocele relapse is also possible. These complications make disability and hospitalization periods longer [Malysheva et al. 2005, Guzenko et al. 2007, Dovgilev 2010, Rowe et al. 2016]. Lord's technique, unlike von Bergman and Winkelmann's operations, requires no separation of the hydropic swelling from the surrounding tissue and, due to this, allows to make the wound surface

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smaller and to practically eliminate damage to blood and lymphatic vessels, thus reducing the number of postoperative complications [Lord 1964, Cimador et al. 2010, Rowe et al. 2016].

A review of the literature on this subject [Grinev et al. 2005, Dovgilev 2010; Yang et al. 2015, Yin et al. 2015, Peng et al. 2015, Sim 2015] found that the unsatisfactory outcomes of conventional approaches to hydrocele necessitated resorting to scrotoscopy and video endoscopy, the use of laser and radio wave scalpels.

The sclerotherapy is considered a non-invasive method[Malysheva et al. 2005, Shan et al. 2011, Metcalfe at al. 2014]. However, despite fewer complications, less postoperative pain, and a more attractive price, the main disadvantages are repeated sclerotherapy sessions and a rather high rate of relapse, which made such methods less valuable.

Proceeding from the above, this research endeavoured to apply the improved sclerotherapy technique to 34 patients. The obtained results show that there was only 1 relapse of hydrocele, which appears a very promising outcome. A small amount of ethanol (5–10 ml) additionally injected in the scrotum afterwards seems to prolong the effects of alcohol on the scrotum tunic tissues.

Although it remains debatable how ethanol impacts the tunic and testicular tissues, it can be said that spermogram data argues for the safety of ethanol for testicular the tissues points to unchanged ejaculate parameters prior to and after the sclerotherapy [Malysheva et al. 2005, Shan et al. 2011]. That is why the testicular tissue morphology in these patients was studied before the operation and in 4–6 months after the operation. The findings demonstrate that no impairment of spermatogenesis occurred due to the therapy, which confirms safety of the improved sclerotherapy. Besides, the results of ejaculate analysis revealed no difference in the parameters before and after the therapy.

In case of the conventional operations, the post-operational infiltrate in the scrotum was revealed in 28 patients (48.3%) in 2 months after the treatment or later, while after the sclerotherapy there was none.

As compared to the improved sclerotherapy, the tolerability of standard operations and conventional sclerotherapy is reliably poorer, which is associated with surgical injury of the former and the repeated sessions of the latter.

It is known that hydrocele impacts testicular volume thus impairing its blood supply. Thus, according to Mihmanli et al. (2004), the Doppler sonography detected an increased volume of testicles and higher resistivity and pulsatility indices on the affected side in hydrocele patients; although these parameters were largely stabilised after the therapy. Based on the to sonography data, Adaletli et al. (2006) detected a reliable difference in the testicle volume between the healthy (0.62±0.24 ml) and the affected side (0.72±0.26 ml) in child patients. After the operation, the testicle volume on the hydrocele side reduced to 0.60±0.21 ml. According to that study, the testicle volume reduction was about 15% postoperatively. Dovgilev (2010) also noted poorer blood supply on the affected side in hydrocele patients.

The ultrasonographic data, obtained during this study in 6–12 months after the operation, confirm the findings of the researchers. The total testicle volume on the hydrocele side was 20.9±1.5 cm^3, although it was 25.2±2.2 cm^3

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preoperatively. This difference in values before and after the sclerotherapy is found to be statistically reliable ($p<0.05$). Therefore, a change to haemodynamics on the hydrocele side, if compared with the healthy side, accompanies the reduction in the testicle volume. It can be associated with better lymph circulation both in the testicular vaginal tunic and in its parenchyma, a smaller oedema, and better blood flow.

V. CONCLUSION

The evidence from this study suggests that the improved sclerotherapy with 96% ethanol has a number of advantages:

First, it allowed minimizing the relapse rate and the need for repeated therapy sessions.

Second, it eliminated haematomas and wound abscesses and reduced the number of early postoperative complications, such as epididymitis — down to 4% in comparison to 20.2% after the standard operations; oedemas and scrotum infiltrations— from 65.5% down to 8.3%.

Third, this method had no adverse effect upon the testicle tissue. On the contrary, it conduced to better blood supply and lymph efflux from the parenchyma, which can be confirmed by the results of testicle morphology analysis, normalised testicle volume, parameters of the average arterial blood flow and the resistivity index according Doppler sonography data, and the absence of reliable change in the spermogram. As for the remote complications (in 2 months and later), there was revealed a reliable reduction in the rate of postoperative infiltrates in the scrotum and spermatic cord and less pain syndrome after the administering the improved sclerotherapy if compared with the conventional techniques (4.1% after the improved sclerotherapy against 48.3% after the conventional operations, and 2.1% against 25.7%, respectively).

These findings concerning the efficiency and safety of the ethanol sclerotherapy appear very promising. Although further randomised research will need to be performed, we recommend this technique for hydrocele patients over 40 years old.

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