

INJECTION SCLEROTHERAPY: AN ALTERNATIVE TREATMENT TO HYDROCELECTOMY FOR PRIMARY HYDROCELE

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Abstract

Background: A hydrocele is an abnormal collection of serous fluid between the two layers of tunica vaginalis of testis. It can either be congenital or acquired. Surgical treatment has been the gold standard and widely accepted for management of hydrocele. Surgery can lead to sexual dysfunction. Patients who are not fit for surgery can undergo aspiration and sclerotherapy of the hydrocele using variety of sclerosing agents. This study aims at comparing results and complications of standard surgery (Hydrocelectomy) and injection sclerotherapy (IS) using sodium tetradecyl sulphate (STDS) as sclerosing agent. **Materials and Methods:** 50 consecutive male patients aged ≥ 18 years of hydrocele admitted in General surgery wards of N.S.C.B. government medical college Jabalpur, a tertiary care hospital, were included in prospective nonrandomised manner from January 2020 to December 2021, between two arms of study. Clinical examination and USG scrotum established the diagnosis of hydrocele before treatment. Patients were followed up for 6 months. Complications and any recurrence of symptoms were recorded. Repeat sclerotherapy was done in recurrent cases after failed sclerotherapy. No upper limit of sessions of IS was decided. After 6 month of failed sclerotherapy treatment, patients underwent surgery. Statistical analysis was done using chi square test. Contiguous data were expressed as mean and standard deviation. Statistical significance was considered as $p < 0.05$. **Result:** 25 patients were included in each arm. Mean age of patients in IS arm was 42.68 years and 37.92 years in surgery arm. 6 patients (24%) in IS arm developed recurrence at 1 month follow up. Repeat IS resulted in cure in four of these patients at six months. This resulted in 92% cure rate as compared to 100% cure rate after surgery. Mean hospital stay (no admission Vs 2.8 days) and return to work (day 1 Vs 13.2 days) was significantly shorter in IS group. There were fewer complications in IS group in terms of pain and fever ($p < 0.05$). Incidence of hematoma and infection were not different amongst two arms. **Conclusion:** IS in hydrocele is safe and effective alternative to surgery that has fewer complications and equivalent outcome. Recurrence rate is comparable with additional advantage of no hospitalisation required and early return to work in IS group.

INTRODUCTION

Hydrocele is abnormal collection of serous fluid between the two layers of tunica vaginalis of testis. It can either be congenital or acquired. Though, majority of hydroceles pose little clinical consequences, treatment should be considered if the hydrocele is large or symptomatic. Surgical treatment has been the gold standard and widely accepted for management of hydrocele.^[1,2] Two main surgical techniques are used. The Lords

plication, described in 1964 and the Jaboulay repair in 1902.^[3,4] Minimally access procedures are also described with good patient's satisfaction when compared to conventional eversion-excision hydrocelectomies.^[5,6,7] Surgery can lead to sexual dysfunction. Patients who are not fit for surgery can undergo aspiration and sclerotherapy of the hydrocele using variety of sclerosing agents, which is less invasive, has less morbidity and complications.^[3] Aspiration and sclerotherapy with doxycycline seems as effective and safe as

non-surgical treatment option for hydrocele where the success rate of a single hydrocele aspiration and sclerotherapy procedure is claimed to have the same success rates involving hydrocelectomy while avoiding the hospital expense and many other complications.^[5] Other studies reported lower success rate and less patient's satisfaction than hydrocelectomy.^[8,9] Many sclerosing agents have been described including tetracycline, sodium tetradecyl sulphate (STDS), polidocanol, fibrin glue, phenol, OK-432, ethanolamine oleate, antazoline, rifampicin, and talc.^[8] Sclerotherapy limits the production of fluid, which results in coaptation of the walls.^[8] Very few reported studies exist which compare hydrocelectomy with aspiration and sclerotherapy. We conducted a study to compare aspiration and sclerotherapy (IS) using sodium tetradecyl sulphate (STDS) with open hydrocelectomy in the treatment of hydrocele with regard to safety, efficacy and cost effectiveness. STDS is cheap, readily available and has been used safely and extensively.

MATERIALS AND METHODS

50 consecutive male patients aged ≥ 18 years of hydrocele admitted in General surgery wards of N.S.C.B. government medical college Jabalpur, a tertiary care hospital, were included in a prospective nonrandomised manner from January 2020 to December 2021. Clinical examination and ultrasound imaging of scrotum was done to confirm the diagnosis. Patients with previous scrotal surgery and secondary hydrocele were excluded from study. Patients were divided into two study arms in nonrandomised manner, 25 patients for injection sclerotherapy and 25 patients for hydrocelectomy arm each. Jaboulay's procedure was done in patients of surgical arm.

Aspiration and sclerotherapy were done as outpatient procedure using 18 gauge needles under aseptic conditions. Local anaesthesia using lignocaine 2% was injected with 24 gauge needles at the puncture site. Patients remained in normal clothing and without shaving. The puncture area was identified by transillumination of the scrotum with care taken to avoid damage to blood vessels. Aspiration of all the fluid was done and cannula left in situ to instil STDS and xylocaine mixture. Complete emptying was ensured by manipulation of the scrotum before instillation. We took a mixture of equal volumes of xylocaine 2% and STDS, to 10% of the total aspirated volume. Aspirated fluid was sent for cytological analysis. Tight scrotal bandaging was done after the procedure. Intravenous single dose of coamoxiclav 1.2 gram was given to all patients. Analgesics were given as per the need of patients. Patient were followed on 7th day, 1 month and 6 months after the procedure by clinical examination and scrotal ultrasonography.

On follow up pain was assessed according to visual analogue scale (VAS). Fever and scrotal tenderness were considered as signs of infection. Any recurrence and hematoma were assessed on clinical examination and USG scrotum. Repeat aspiration and sclerotherapy was done for recurrence after ruling out hematoma. All patients were followed up for maximum six months. After 6 months of repeated failed sclerotherapy, patients were considered for surgery. Cure was considered, if scrotal size was normal and testis separately palpable with negative trans-illumination test.

Statistical analysis: all continuous data were expressed as mean and median. All categorical data were expressed as proportion and percentage. Chi square test was done to find the statistical significance amongst two arms. P value of <0.05 was considered significant.

Prior approval was obtained from institutional committee of ethics.

RESULTS

Patients in two arms were comparable in terms of mean age (IS group was 42.68 years while in surgery group it was 37.92 years, $t=1.116$; $P>0.05$) and scrotal sac fluid volume ($t=1.572$; $p>0.05$). Patients in IS arm didn't require any hospitalization as compared to mean 2.8 days hospitalization in surgery arm. Patients of IS arm were able to work from the same day as compared to the surgery arm where mean 13 days were needed for resumption of work. [Table 1]

Recurrence or persistence of hydrocele at one month was noticed in 6 (24%) patients, four of these resolved after repeat IS. Overall recurrence rate was 8% in IS group as compared to 0% in hydrocelectomy group, though not statistically significant. Overall cure rate in IS group was 92% and 100% in hydrocelectomy group.

Fever and pain were significantly less in IS group at 7th day, one month and six months. 5 patients in hydrocelectomy group had some form of infection as compared to one patient in IS arm, however it didn't reach statistical significance. Prevalence of early hematoma within 7 days was equal in both arms but it was more frequent in IS group at 1 and 6 months follow up, this difference was not statistically significant. [Table 2]

Patients in IS group were divided into three subgroups, mild volume category (0-50ml), moderate volume (50-99 ml) and gross volume (>100 ml). There was no recurrence in mild volume category. 20% patients (1 out of 5) in gross volume and 39% (5 out of 13) in moderate volume category developed recurrence at one month. [Table 3]

There were no complications associated with repeat aspiration and sclerotherapy in mild volume and gross volume category.

Table 1: comparison between two arms with respect to age, aspirated volume, hospital stay & work resumption

Factor	IS arm	Surgery arm	Significance
Aspirated Volume(ml.)	78.80 ± 43.236	96.00 ± 33.541	t=1.572;p>0.05
Hospital Stay (Days)	0.00 ± 0.00	2.84 ± 1.724	t=8.235;p<0.0001
Work Resumption (Days)	0.00 ± 0.00	13.08 ± 7.527	t=8.688;p<0.0001

Mean aspirated fluid volume was similar in both groups. Work resumption was significantly less in IS group.

Table 2: Comparison of outcome in terms of complications and recurrence

Total No. of Patients		Injection Sclerotherapy (IS) (%)	Hydrocelectomy (%)	Significance
		25	25	
Fever	7 D	3 (12.0)	9(36.0)	$\chi^2=3.947;p<0.05$
Pain	7D	10 (40.0)	16 (64.0)	$\chi^2=2.885;p<0.05$
	1 M	2 (8.0)	7 (28.0)	$\chi^2=3.388;p<0.05$
	6 M	0 (0.0)	4 (16.0)	$\chi^2=4.347;p<0.05$
Infection	7D	1 (4.0)	5 (20.0)	$\chi^2=3.0303;p>0.05$
	1 M	0 (0.0)	0 (0.0)	$\chi^2=0.00;p>0.05$
	6 M	0 (0.0)	0 (0.0)	$\chi^2=0.00;p>0.05$
Hematoma	7D	4 (16.0)	5 (20.0)	$\chi^2=0.136;p>0.05$
	1 M	5 (20.0)	2 (8.0)	$\chi^2=1.495;p>0.05$
	6 M	3 (12.0)	0 (0.0)	$\chi^2=3.191;p>0.05$
Recurrence	1 M	6 (24.0)	0 (0.0)	$\chi^2=6.818;p<0.01$
	6 M	2 (8.0)	0 (0.0)	$\chi^2=2.083;p>0.05$

Table 3: Cure rate after injection sclerotherapy according to volume

Aspirated Volume (ml)	0 – 50	50 – 99	> 100
Total No. Of Patients	7	13	5
Cure Rate (Percentages)	7 (100%)	8 (61%)	4 (80%)
t=2.85; P<0.05 (0-50 v/s 50-99, 50-99 v/s >100)			

DISCUSSION

An acquired hydrocele affects approximately 1% of men and is mostly seen after age of 40 years.^[10] Tumors, infection or trauma are important causes of acquired hydrocele, but most are idiopathic in origin. Hydrocele may result from increased serous fluid secretion, or failure of lymphatics in the mesothelial lining to reabsorb fluid.^[11] Aspiration alone results in recurrence in almost all patients. Sclerotherapy is necessary after aspiration to create the inflammatory response and subsequent fibrosis which impede the flow of fluid into the hydrocele sac, thereby more effectively preventing recurrence.^[5]

Minimally invasive approaches to treatment of any disease are preferred over conventional surgical approach provided these are equally effective and safe. Patient satisfaction, low morbidity, reduced cost, and early return to work are primary goals in hydrocele treatment. Aspiration and sclerotherapy represents a minimally invasive approach to the treatment of hydrocele. Patient numbers in most of the available studies are relatively small with different variables within these studies, making comparison difficult. Different combination and concentrations of sclerosant agents, varying concentration of local anaesthetic agent and other additives are described. There is also great variation in the size of the hydrocele being treated. Larger hydroceles treated with aspiration and sclerotherapy have a greater chance of needing second aspiration and sclerotherapy. Cure is also not very well defined, so the follow up schedule.

Hydrocelectomy is considered the gold standard treatment of hydrocele and remains to be most efficient treatment modality. Hydrocelectomy is a procedure which needs to be carried out in the operating room, often with spinal or general anesthesia. Larger hydroceles that undergo surgical repair have a greater chance of complications as well. Hydrocelectomy may be a preferred option in young adults for the possible complication of chemical epididymitis with IS.^[12,13]

Reported success of aspiration of hydroceles with STDS sclerotherapy ranges from 44% to 100%.^[1] However, the definitions of success have been inconsistent, as have the number of procedures employed by different investigators. For example, some studies have reported success rates based on one treatment, whereas others have utilized as many as five procedures before deciding whether the treatment was successful. Beiko et al,^[9] reported 75% patients were treated successfully with aspiration and sclerotherapy. Shakiba et al,^[14] reported in a systemic review, a significant increase in recurrence in those who received sclerotherapy compared with surgery (3 studies, 196 participants: RR 9.37, 95% CI 1.83 to 48.4). In our study 76% patients were cured after first injection sclerotherapy. Second IS improved cure rate by 16% to overall cure in 92%. The success of sclerotherapy was 47.5%, 30%, 12.5%, 5% and 2.5% after 1st, 2nd, 3rd, 4th and 5th injection respectively in study by Shan at al.^[12] In a study by Erdas et al,^[13] 41.7% patients required more than one injection sclerotherapy session to obtain cure. Although multiple IS sessions may increase inconvenience to the patients and possibility of complications, there

are no clear guidelines for maximum number of IS sessions. None of our patients developed any complication after repeat IS.

In this study, return to normal daily activity is immediate in injection sclerotherapy group, that is statistically significant. Shan et al,^[11] reported similar results, in their study recovery after hydrocelectomy was around 15 days as compared to immediate recovery after injection sclerotherapy. Aspiration and sclerotherapy were largely abandoned until the report of Maloney who showed a 36% success rate after a single injection sclerotherapy using phenol and a full cure after 2 or three injections in 1 hydrocele study. Since than many sclerosant material have been described for treatment of hydrocele. Earlier use of IS was restricted for patients of hydrocele with fluid volume less than 100 ml, yet recent reports claimed successful sclerotherapy in large hydroceles of a volume of up to 1200 ml. This is comparable to our study, where there is no correlation between hydrocele fluid volume and cure rate in injection sclerotherapy group.

Fever and pain were significantly less in IS group in our study. Agrawal et al,^[15] reported similar results. In systemic review by Beiko et al, one study reported a non-significant decrease in fever in the sclerotherapy group (60 participants: RR 0.25, 95% CI 0.06 to 1.08). There was an increased number of infections in the surgery group, however this increase was not statistically significant (4 studies, 275 participants): RR 0.31, 95% CI 0.09 to 1.05; $I^2 = 0\%$). Three studies reported the frequency of pain in the surgery group was higher than aspiration and sclerotherapy group.

Although incidence of hematoma was slightly more in IS group, but it was not statistically significant. In systemic review by Beiko et al, there was no significant difference in haematoma formation between the two groups (3 studies, 189 participants: RR 0.57, 95% CI 0.17 to 1.90; $I^2 = 0\%$).

In Shan et al,^[12] study sperm analysis was done before the treatment and at one, three and twelve months after the sclerotherapy in 22 patients, they found reduction in sperm counts for upto 6 month, with no statistical significance but at the 12th month sperm count returned to baseline.

Limitations of this study is that, patients were not randomized and sample size was small. Cure rate was less after first session of IS as compared to the cure rate reported by many authors, this could be due to differences in concentration of sclerosant agents.

CONCLUSION

Aspiration and sclerotherapy using STDS represents a minimally invasive approach to the treatment of hydroceles that is simple, safe, and reasonably effective. As this study and most other studies

suggest that complication in terms of fever, pain and infection are less with IS, further these patients do not require hospitalization with almost immediate relief of their symptom and early resumption of activity. However operative treatment comes with 100% cure rate. Repeated session of IS improved cure rates without any significant increase in complications. IS may be a good alternative approach for patient, who are poor surgical candidates, and who need early resumption of work. Hydrocelectomy is the intervention of choice in younger patients and in those patients, where follow up is difficult.

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