International Surgery Journal
Roy A et al. Int Surg J. 2017 Dec;4(12):3884-3889
http://www.ijsurgery.com
pISSN 2349-3305 | eISSN 2349-2902

DOI: http://dx.doi.org/10.18203/2349-2902.isj20175071

Original Research Article

Aspiration sclerotherapy: a novel and cost-effective approach to the management of hydroceles in a developing country

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Received: 13 October 2017
Accepted: 24 October 2017

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ABSTRACT

Background: The present study was carried out with an aim to perform a prospective study to establish the role of sodium tetradecyl sulfate (3 %) (STDS) as a safe and effective sclerosant in the management of primary hydroceles.
Methods: Sclerotherapy was performed with 3 % STDS on an outdoor basis. The amount of sclerosant injected depended on the amount of fluid drained. All patients were given prophylactic antibiotics. Patients were clinically reassessed at 1 week, 1 month, 3 months, and 6 months and earlier if complications occurred. All patients were given prophylactic antibiotics. The data were analyzed using Statistical Package for Social Sciences Version 15.0. The data have been represented as frequencies and percentages. Chi-square test was used to compare the data. A total of 57 patients with primary vaginal hydrocele gave consent for being enrolled in the study. The age of patients ranged from 18 to 65 years with a mean age of 35.72±13.18 years.
Results: The success rate at the end of the study was observed to be 84.2 %. As regards patient satisfaction, in present study, in a limited time period of follow up, all the patients who had a successful procedure were satisfied.
Conclusion: Overall, sclerotherapy was observed to be a relatively cost-effective (including both direct and indirect costs) procedure with low complications, high satisfaction, faster return to work and a high success rate within the limited period of follow-up.

Keywords: Hydrocele, Sodium tetradecyl sulfate, Sclerotherapy

INTRODUCTION

Surgical treatment has been the gold standard for management of hydrocele and is widely accepted as the most definitive modality, especially for communicating and loculated hydrocele. However, it is traumatic, painful, and associated with prolonged convalescence.[1,2] The surgical procedures commonly used for the treatment of hydrocele are excision of sac, plication of sac (Lord's operation),and eversion of sac (Jaboulay's procedure).[3-5] Simple repeated aspiration of primary vaginal hydroceles may keep the patient comfortable, but increases the risk of infection and recurrence.[6] The common complications observed during the surgery of hydrocele are bleeding, injury to the cord structures and epididymis, and torsion of the testis after a faulty positioning postoperatively. While considering the treatment of hydroceles, we should be guided by the aims such as patient satisfaction and convenience, time taken off work, and reduced cost to health care systems as well as patients. Surgical procedures are associated with complications of anesthesia and surgery. Moreover, hospital admission is usually required, thus affecting the health and economy of the patient. In recent years, there has been a paradigm shift in the minimally invasive approach in the treatment of various diseases. Aspiration sclerotherapy remains a minimally invasive approach to the treatment of hydroceles. Sclerotherapy has grown in popularity as it is a safe, effective, and painless outdoor procedure and also economically beneficial for the patient. Not only is the

cost of therapy low; but also the patient can return to work the same day, which is beneficial for the daily wage earner. Our aim to perform a prospective study to establish the role of sodium tetradecyl sulfate (3%) (STDS) as a safe and effective sclerosant in the management of primary hydrocele.

METHODS

The present study was conducted in the outpatient department of Department of Surgery at KPC Medical College and Hospital. The period of study ranged from 1 January 2014 to 31 August 2015. Patients of unilateral/bilateral vaginal hydrocele were included in the study.

Inclusion criteria

- Subjects reporting with unilateral or bilateral primary vaginal hydrocele
- Those willing to participate in the study and providing informed consent

Exclusion criteria

- Subjects with secondary vaginal hydrocele (secondary to trauma, malignancy, or epididymorchitis), communicating hydrocele, infected hydrocele
- Those below 12 years of age
- Subjects having a positive history of previous intervention (sclerotherapy or operation) and/or uncontrolled diabetes mellitus
- Subjects not consenting to participate

Sclerotherapy was performed on an outdoor basis. Routine blood tests and urine analysis for routine and microscopy were done. Ultrasonography of scrotum was done in selected cases where testicular tumor was suspected clinically. After painting the scrotum with povidone iodine solution, draping was done. Before puncture, the site was identified by trans illumination to avoid injury to the testis. Scrotal puncture was done by a 20-G venous cannula and fluid drained with a 20-cc disposable syringe. After aspiration of the entire contents of the sac, it was injected with 3% STDS. The amount of sclerosant injected depended on the amount of fluid drained. For ≤200ml of fluid 2 ml of STDS was used; for 201-300ml, 3ml of STDS was used; for >300ml of fluid drained, 4ml of STDS was injected. Four milliliters were the maximum dose, and not more than 4 ml was used under any circumstances. After injection of the sclerosant, the two layers of the sac were opposed. All patients were given prophylactic antibiotics (Ciprofloxacin-500mg) twice daily for 5 days. Only Paracetamol was prescribed as and when required. No other anti-inflammatory drug was given. Patients were clinically reassessed at 1 week, 1 month,3 months, and 6 months and earlier if complications occur. At each review, they were interviewed on pain, recurrence, complications (edema, hematoma, wound infections), and resumption of work. Patients in whom fluctuation and trans illumination were persisting after 1 month were given a second dose of sclerosant. Hydrocele was considered cured when they no longer had fluid on fluctuation test and trans illumination was negative on clinical examination. Fluctuation and trans illumination persisting after 3 months was taken as failure and surgery was advised. The outcome was measured as:

- Complications-viz. pain, infection, edema, and hematoma formation
- Need of surgery.

RESULTS

Between 1 January 2014 and 31 August 2015, a total of 376 patients with hydrocele attended the surgical OPD of KPC Medical College and Hospital. Of them, 126 patients satisfied the inclusion criteria. After proper counseling, a total of 57patients with primary vaginal hydrocele gave consent for being enrolled in the study. The age of patients ranged from 18 to 65 years with a mean age of 35.72±13.18 years. Maximum number of patients were in the age group of 21-30 years (n=17; 29.8%). Only eight (14.0%) patients were aged either up to 20 years or above 50 years.

Table 1 shows distribution of subjects according to the amount of fluid drained. In maximum number of patients (n=18; 31.6 %), the amount of fluid drained was between 51and 100 ml. There were 12 (21.1%) subjects in whom the amount of fluid drained was 151-200ml. In a total of ten (21.1%) patients, the amount of fluid drained was 101-150ml, whereas in nine (15.8%) patients, the amount of fluid drained was ≤50 ml. A total of 8 (14.0%) patients had >200ml of fluid drainage.

Table 1: Distribution according to amount of fluid drained.

Amount of fluid drained	No.	Percentage
≤50ml	9	15.8
51-100ml	18	31.6
101-150ml	10	17.5
151-200ml	12	21.1
>200ml	8	14.0

In maximum number of patients (n=18; 31.6%), the amount of fluid drained was between 51 to 100ml. There were 12 (21.1%) subjects in whom the amount of fluid drained was 151-200 ml. In a total of 10 (21.1%) patients the amount of fluid drained was 101-150 ml whereas in 9 (15.8%) patients the amount of fluid drained was <50 ml. A total of 8 (14.0%) patients had >200 ml of fluid drainage.

Table 2 shows the distribution of subjects according to dosage of STDS given. Majority (87.7%) of subjects

received only 2 ml of STDS, there were six (10.5%) subjects who received 3ml of STDS, whereas 1 (1.8%) subject received 4 ml of STDS.

Table 2: Distribution of subjects according to amount of STDS given (ml).

Amount of STDS	No.	Percentage
2 ml	50	87.7
3 ml	6	10.5
4 ml	1	1.8

Majority (87.7%) of subjects received only 2ml of STDS, there were 6 (10.5%) subjects who received 3ml of DTDS while 1 (1.8%) subject received 4 ml of DTDS.

None of the patients reported to have drug reaction. No incidence of pain, infection, edema, or hematoma formation was observed.

At first follow-up

The first follow-up took place at 1 week. Table 3 shows the follow-up findings at 1 week.

A total of 32 (56.1%) patients had no relevant finding. Redness and inflammation (R + I) was present in 25 (43.9%) cases.

Table 3: Follow up findings at first week.

Finding	No. of cases	Percentages
None	32	56.1
R + I	25	43.9

Table 4: Outcome at first month.

S. No.	Finding	No. of cases	Percentages
1.	Cured	36	63.2
2.	Failed	21	36.8

At second follow-up

At the second follow-up, none of the patients reported of any complaints. Table 4 shows the outcome of the second follow-up findings at 1 month. The success rate at second follow-up (at 1 month) was observed to be 63.2 %. However, a total of 21 (36.8 %) patients did not show positive response to sclerotherapy and were labeled as failed cases. Aspiration sclerotherapy was done again as per previous protocol in all the 21 failed cases while the remaining patients were followed up at 2 months.

At third follow-up

At the third follow-up, none of the patients had any complaint. No change in status was observed among those who were successful in the first dose itself. The outcome of 21 patients in whom the procedure was repeated (second step) has been shown in Table 5. Of the 21 patients in whom the procedure was repeated, 12 (57.1 %) were cured. Overall, of the 57 patients enrolled, a total of 48 (84.2).

At fourth follow-up

At the fourth follow-up, none of the patients showed any complication. However, no change in success rate as observed at the third follow-up was observed. Table 6 shows the distribution of patients according to need of surgery. A total of nine cases which were declared as failed required surgery. A total of 32 (56.1%) patients had no relevant finding. Redness and inflammation was present in 25 (43.9%) cases.

The success rate at 2nd follow up (at 1 month) was observed to be 63.2%. However, a total of 21 (36.8%) patients did not show positive response to sclerotherapy and were labelled as failed cases.

Table 5: Outcome at third follow up.

Finding	Total (n=57)	%	Repeat procedure (n=21)	%
Cured	48	84.2	12	57.1
Failed	9	15.8	9	42.7

Out of 21 patients in whom the procedure was repeated, 12 (57.1%) were cured. Overall out of 57 patients enrolled, a total of 48 (84.2%) were cured. Thus, the overall success rate of the procedure was 84.2%.

Table 6: Need of surgery.

Need of Surgery	No. of cases	Percentages
No need	48	84.2
Surgery required	9	15.8

DISCUSSION

With the development of medical and surgical sciences in the recent years, there has been a paradigm shift toward medical management of surgical problems as a preliminary tool in the armamentarium of a surgeon. When considering the treatment of hydroceles, we should be guided by aims such as patient satisfaction and convenience, time taken off work, and reduced cost to health care system as well as the patients. A number of sclerotherapy options have been suggested in literature such as tetracycline, polidocanol, antazoline, OK-4329, quinacrine, ethanolamine oleate, phenol, and fibrin glue with variable results.[9-13]

In present study, we have reported the results of sclerotherapy using STDS which has shown to be having promising results in long-term follow-up.[14] A total of 57 patients were enrolled in the study distributed along all age groups. Hydrocele has been reported to occur in

males at any age, although it tends to occur at the extreme ends of the age spectrum. Baby boys may start life with a communicating hydrocele, while elderly men are prone to developing a buildup of fluid in the testicular sac.[15] In the present study, we had patients ranging from 18 to 65 years of age, thus incorporating a spectrum of age profiles.

In the present study, majority of subjects (89.5 %) had unilateral involvement; there were only six (10.5 %) cases with bilateral involvement. In a study by Bhumiratana et al, the incidence of bilateral involvement was observed to be 10 %. However, Latif et al, in their study among 50 patients of hydrocele found the incidence of bilateral involvement to be 2 % only.[16,17] Similarly, Fuse et al. reported none of their 15 patients to be having bilateral -involvement.[18] Agrawal et al. also did not report a single case with bilateral involvement.[19] It is difficult to comment whether all these studies had selected patients with unilateral involvement only, as these studies were comparative studies, and hence, in order to rule out any confounding effect, they might have excluded the bilateral involvement. As such, there is limited literature available regarding the incidence of bilateral involvement.

In the present study, we had followed a treatment protocol involving aspiration followed by sclerotherapy. The amount of fluid drained was between 51 and 100 ml in maximum number of patients (n=18; 31.6%); however, a total of eight (14.0%) patients had >200ml of fluid drainage. These findings are in consonance with the findings of Jamaluddin et al. who reported drainage of 51-100ml of fluid in 28 % of their patients, whereas fluid drainage >200 ml was reported to be 16%.[20] The amount of fluid drained reflects the severity of the problem, and some workers have based their sclerotherapy protocol on the amount of fluid drained. Latif et al. fixed the criteria for dosage of TDS sclerotherapy on the basis of amount of fluid drained- they fixed the following criteria:[17]

- 2ml for <100ml aspirate
- 3ml for <100 200 ml aspirate
- 5ml for >200ml aspirate

In the present study too, the amount of sclerosant injected depended on the amount of fluid drained. For ≤200 ml of fluid, 2 ml of STDS was used; for 201–300 ml, 3 ml of STDS was used; for >300 ml of fluid drained, 4 ml of STDS was injected. Four milliliters was the maximum dose, and not more than 4 ml was used under any circumstances. The upper limit of dose was fixed as per the recommendations of the manufacturers who have recommended against the use of >4 ml of dose in a single session. In the present study, majority of subjects had ≤200ml of aspiration of fluid; hence, the dose of 2ml was used in majority (87.7%). Dose of 4 ml was required in only one (1.8%) patient. In the present study, we did not find any drug reaction in any of our patients. These findings are in agreement with the findings of Latif et al. and Hanif et al. who too did not report any drug reaction in any of their patients.[17,21]

On follow-up, 25 patients (43.9%) were found to be having local redness. Prophylactic antibiotics were prescribed (Cipro floxacillin 500 mg B.I.D. for 5 days) in all cases. Rashes are one of the common complications of STDS, but none of our patients developed generalized rashes. The patients were again followed up after 1 month. At 1 month, 21 of the 57 (36.8%) patients showed recurrence, thereby indicating the failure of procedure. A failure rate of 40 % at first attempt has been reported by Latif et al. which is close to the findings of the present study.[17] Khaniya et al, have also reported a similar rate of recurrence (34.6%) at a follow-up of 3 months. Rencken et al. too reported a similar recurrence rate (36%).[22,23] However, the results of Beiko et al, who evaluated the success in terms of partial success and complete success, reported a recurrence rate of 24% only.[24] Brasilis and Moss carried out a 9-year prospective study and reported an initial success rate of 76%. The relatively higher success rate of Brasilis et al. could be attributed to relatively larger sample size and relatively higher experience gained by the authors through their exceptionally longer duration of study.[25]

Aspiration sclerotherapy was done again as per previous protocol in all the 21 failed cases while the remaining patients were followed up at 2 months. At the third follow-up, none of the patients had any complaint. No change in status was observed among those who were successful in first dose itself. The outcome of 21 patients in whom the procedure was repeated showed the recurrence in nine (15.8%) cases.

These results are in accordance with the findings of Latif et al, Rencken et al, Brasilis et al, and Beikoet al.[24,26-28] All have reported the success rate between 80 and 95% after second dose of sclerotherapy. The reason for recurrence could be attributed to incomplete aspiration or inability to sclerosed the concerned area completely. In a study by Erdas et al, 41.7% patients required more than one injection to obtain cure.[29]

In present study, we did not find even a single case with complaints of pain or hematoma formation, although some of the authors have reported the incidence of pain to be 24%. The reason could be the administration of analgesics and antibiotics in the post-procedure period.[17]

None of the patients required hospital stay. The cost of the treatment was only Rs 120/−(about $2) for single visit, whereas for those who had to be administered second dose, the cost became Rs 240/−(about $4). This cost is much below the cost of surgery for hydrocele, which costs around Rs 2,500/− to Rs 3,000/− ($40 to 50) in a setup like ours. Thus, from the point of view of the cost, sclerotherapy is almost available at almost one eighth of the cost of surgery. Leaving apart the direct costs, the indirect costs in terms of hospital stay, and loss

of work opportunities, sclerotherapy turns out to be a much cheaper and convenient offer.

Although the present study was not a comparative study, yet in previous studies the comparison between surgical procedure and STD did not show a significant difference between the two; rather, some of the workers have shown the sclerotherapy to be having higher success rate as compared to surgical procedure.[17, 20–22, 24] However, some other workers such as Beiko et al. have reported a better satisfaction and success rate of surgical procedure over STDS sclerotherapy.[24] Despite this, Beiko et al, have found sclerotherapy to be a better option owing to its low complications (8%) as compared with surgical option (40%).

As regards patient satisfaction, in present study, all the patients who had a successful procedure were satisfied. The satisfaction rate quoted by different workers varies. Beiko etal. have reported a satisfaction rate of 75% for sclerotherapy as against 88% for hydrocelectomy, whereas Khaniya et al, have reported a much higher gap between sclerotherapy and surgical options (61.9 and 95%, respectively).[24,22] However, in a study by Stattin et al, a much higher satisfaction rate over a long term (mean40 months) was observed among patients undergoing STD sclerotherapy for hydrocele. They reported a satisfaction rate of 95%. However, in present study in a limited time period, all the patients who had a successful procedure were satisfied.

Thus, sclerotherapy emerges out to be a first line of treatment options for patients with primary vaginal hydrocele. Owing to the ability of procedure to be carried out as an office procedure, low rate of complications, low cost, reasonable success rate, and low inconvenience to patient, it is the treatment of choice both for the patient as well as for the treating surgeon. Although long-term follow-up could not be carried out in present study, the historic data suggest its long-term utility too. A comparative study with longer duration of follow-up and inclusion of an objective criterion for patient satisfaction is recommended so that the efficacy of different treatment options could be compared in similar environment. It is recommended that the cases in present study should be followed up further for recurrence in order to ascertain the long-term efficacy of the treatment offered in our setup.

CONCLUSION

Overall, sclerotherapy was observed to be a relatively cost effective (including both direct and indirect costs) procedure with low complications, high satisfaction, and a high success rate within the limited period of follow-up.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the institutional ethics committee

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Cite this article as: Roy A, Jain V, Majumdar J. Aspiration sclerotherapy: a novel and cost-effective approach to the management of hydroceles in a developing country. Int Surg J 2017;4:3884-9.