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Comparison of aspiration-sclerotherapy with hydrocelectomy in the management of hydrocele: A prospective randomized study

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ABSTRACT

Background: Hydrocelectomy is practiced as the gold standard technique for the treatment of hydrocele worldwide. Aspiration and sclerotherapy is cheap, less invasive and safe compared to hydrocelectomy. However, the outcomes are inconsistent because of lack of uniformity in methods and sclerosing agents used.

Materials and methods: This was a randomized controlled study conducted in a university hospital for a period of one year. Sixty symptomatic adult males without fertility concern or coexisting scrotal pathology were enrolled. Aspiration and sclerotherapy and hydrocelectomy were performed in 30 each. Primary outcome measures: incidence of complications, loss of working days, cost involved, recurrence rate and patient's satisfaction. Patients were followed up till 6 months after the procedures.

Results: Eight patients (26.7%) after hydrocelectomy developed fever which was significantly more ($p < 0.05$) than 2 patients (6.7%) following sclerotherapy. Four patients (14%) with hydrocelectomy had infection ($p < 0.05$). The incidence of pain and haematocele between the two groups were comparable. Nine patients (34.6%) after sclerotherapy developed recurrence at 3 months. All patients developed recurrence after repeat aspiration and sclerotherapy. The level of satisfaction was more in hydrocelectomy 19 (95%) versus 13 (61.9%) patients in sclerotherapy ($p < 0.05$). The cost involved was fivefold and the loss of working days sevenfold in hydrocelectomy ($p < 0.01$) as compared to sclerotherapy.

Conclusion: Although aspiration and sclerotherapy had less complications, morbidity and was cheaper, it had lower success rate and less patient's satisfaction than hydrocelectomy.

1. Introduction

Primary vaginal hydrocele is a benign scrotal condition, resulting from abnormal fluid collection between the layers of tunica vaginalis of testis. Though, majority of hydroceles pose little clinical consequences, treatment should be considered if the hydrocele is large or symptomatic. Various modalities are used to treat the hydrocele. Although hydrocelectomy is considered the gold standard technique, there has been renewed interest in cheaper alternatives like aspiration and sclerotherapy, which is less invasive, has less morbidity and complications.[1,2] A number of chemicals have been described in the literature as sclerosants including tetracycline,[1] sodium tetradecyl sulphate(STDS),[2] polidocanol,[4] fibrin glue,[5] phenol,[6] OK-432,[7] ethanolamine oleate,[8] antazoline,[9] rifampicin,[10] and talc.[10] The basic idea with sclerotherapy is to limit the production of fluid by instillation of a sclerosing solution into the sac, which results in coaptation of the walls. However, the outcomes are inconsistent because of lack of uniformity in method and/or sclerosing agent used.[2–10] Similarly up to date, very few reported studies exist which compared hydrocelectomy with aspiration and sclerotherapy.[2,3] We designed this study to compare the two most popular methods in terms of safety, morbidity, total cost, recurrence and patient satisfaction. We have chosen STDS as the sclerosant for the study as it is cheap, readily available and has been used safely and extensively.[2]

2. Materials and methods

A one year randomized controlled study included all symptomatic adult males of unilateral primary vaginal hydrocele (testicular hydrocele). Patients with fertility concerns or coexisting scrotal haematocele, spermatocele or testicular malignancies were excluded. Out of eighty-two patients who fulfilled the inclusion criteria, 22 patients were unwilling to participate, therefore, sixty patients between 15 and 75 years were studied.

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Table 1
Clinical profile.

	Open hydrocelectomy ($n = 30$)	Aspiration-sclerotherapy ($n = 30$)	p Value
Age (mean ± SD) (range) yrs	36.5 ± 16 (15–66)	39 ± 16.7 (15–75)	0.556
Duration in years (median) yrs	2.5 (0.25–30)	2.7 (0.25–16)	0.10
Hydrocele volume (mean ± SD) (range) ml	318.3 ± 194.97 (50–1000)	219.6 ± 186.47 (50–750)	0.13

The history and physical findings of each patient were assessed. The diagnosis was confirmed by fluctuation and transillumination. Laboratory investigations like hemoglobin, white blood cell count, urine routine and microscopy examination were done in all and the scrotal ultrasound was done when secondary pathologies like testicular tumor or spermatocele had to be excluded.

Patients were divided into two groups of thirty patients each with the help of computer generated random numbers; Group 1 underwent aspiration and sclerotherapy while Group 2 had open hydrocelectomy. The procedures were done with aseptic precautions in both the groups. The aspiration and sclerotherapy was done in the outdoor office for group 1 and patients in group 2 were operated on Day Care Operation Theater. In group 1: aspiration of the fluid was done by a 16 gauze intravenous cannula attached to a 50 ml syringe with a three way stopcock and the sclerosant (sodium tetradecyl sulphate) was injected through the same cannula in situ. The volume instilled was 50% of the aspirated fluid up to the maximum of 80 ml. The sclerosing solution was prepared by diluting the mixture of 4 ml of 3% sodium tetradecyl sulphate and 6 ml of 2% lignocaine hydrochloride with 70 ml of normal saline. The concentration of sodium tetradecyl sulphate and lignocaine hydrochloride in the solution was 0.15% each. In group 2, Jaboulay's procedure (eversion of tunica without excision of sac) was performed under local anaesthesia and drain was not placed. After the intervention, dry dressing with scrotal support was applied for 24 h and oral NSAIDs (tablet combination of paracetamol 325 mg and ibuprofen 400 mg) was prescribed eight hourly for 48 h, then after only on demand basis.

Patients were followed up at 48 h (T_1), 1 week (T_2), 1 month (T_3), 3 months (T_4) and 6 months (T_5), when the incidence of fever, pain, infection, ulceration, haematoma, and recurrence of the swelling was noted. Fever was defined as oral temperature more the 98.6 °F (Fahrenheit). Pain was assessed using visual analogue scale (VAS) of 10 ('0' meaning no pain at all and '10' meaning worst possible pain), and patient scoring ≥3 were considered to have pain. Infection was defined as the presence of either positive microbial culture from wound discharge, or a combination of fever, pain, local erythema and discharge at the incision site. Infection was managed with oral antibiotics and daily dressings till the wound healed. The procedure was repeated after 3 months if there was recurrence following aspiration-sclerotherapy. The outcome was assessed in terms of incidence of complications, total cost involved, loss of working days, recurrence and satisfaction of the patients.

Each patient was asked if he was satisfied with the treatment. The satisfaction was defined if the following criteria were met: decrease in size of hydrocele, relief of any hydrocele related disability, and satisfaction with overall experience and results of the procedure. The approximate cost involved was calculated by addition of all investigations and operative charges, cost of drugs and suture materials. We compared the loss of working days separately and did not include it in the cost of therapy. The recurrence of hydrocele was defined as the reaccumulation of perceptible scrotal fluid with positive transillumination test requiring reintervention after 3 months of procedure.

The collected data was entered in Microsoft excel programme and analyzed by using SPSS 11.5 version. Student t test for differences in mean, Wilcoxan Ranksum test for differences in median, and Chi square test for the parametric variables were applied as appropriate. A p value of less than 0.05 was considered significant.

3. Results

There was no significant difference between the two groups in patients' characteristics like age, duration of symptoms, size, and number of hydroceles (Table 1). The median (interquartile range) age of the patients was 33 years (25–51.7) and the median (range) duration of symptoms before presentation to the hospital in the study population was 2 (0.25–30) years.

There was no difference in the incidence of pain after the intervention between the two groups. Eight patients (26.7%) in group 2 developed fever while which was significantly more ($p < 0.05$) than 2 (6.7%) in group 1. Though, one patient (3.3%) in each group developed haematocele after intervention, the one in group 2 got further complicated and pyocele formed. Four (14%) patients in group 2 developed superficial surgical site infection ($p = 0.03$). The loss of working days (mean ± SD) was 1.1 ± 1.3 and 7.1 ± 4.0 in groups 1 and 2 respectively ($p < 0.001$) (Table 2).

The cost of treatment (median) of hydrocele was NC Rs 300 (US$ 4.3) and NC Rs 1527 (US$ 21.8) in the group 1 and 2 respectively ($p < 0.001$) (1US$=70NC Rs) (Table 3).

Nine patients (34.6%) in group 1 developed recurrence within 3 months. Out of those 9 patients who had undergone repeat aspiration and sclerotherapy at 3 months, only 7 reported for follow up at 6 months and all of them had recurrence. There was no significant difference in age, duration of symptoms and volume of aspirated fluid in the patients with and without recurrence after aspiration and sclerotherapy (Table 4).

At 3 months follow up visit, 16 of 22 (61.5%) and 21 of 26 (95.5%) patients ($p = 0.005$) and at 6 months, 13 of 20 (61.9%) and 19 of 21 (95%) patients ($p = 0.01$) of group 1 and 2, respectively, were satisfied with the treatment (Fig. 1). The reasons of dissatisfaction

Table 2
Complications and activity.

Complications	Hydrocelectomy ($n = 30$)	Aspiration-sclerotherapy ($n = 30$)	p Value
Pain	25(83.3%)	21(70%)	0.22
Fever	8(26.7%)	2(6.7%)	0.03
Infection	4(14.3%)	0	0.03
Haematocele	1(3.3%)	1(3.3%)	1
Loss of working days (mean ± SD)	7.07 ± 3.95	1.13 ± 1.25	0.001

Table 3
Cost.

	Hydrocelectomy ($n = 30$)	Sclerotherapy ($n = 30$)	p Value
Investigation	100 (62–900)	110 (100–600)	0.39
Drugs	200 (100–2000)	240 (130–600)	0.49
Sutures	200 (120–500)	–	–
Operation	1000 (200–1000)	–	–
Total	1527 (715–4000)	300 (250–1200)	0.001

Values are expressed in median (range) (In NC) (1US$ = 70 NC).

Table 4
Recurrence after sclerotherapy.

	No recurrence ($n = 14$)	With recurrence ($n = 7$)	p Value
Age (mean ± SD) years	42.3 ± 19.7	30 ± 10.5	0.11
Duration (median) yrs	0.875	1.6	0.17
Volume (median) ml	125(50–550)	200(50–750)	0.54

at the end of 6 months of therapy in 8 (19.5%) patients were recurrence in 7 patients of group 1 and haematocele and pyocele formation in one patient of group 2. One patient with recurrence in group 1 underwent hydrocelectomy after one year and there was no gross visible effect of the sclerotherapy at surgical exploration.

4. Discussion

The complications like fever and infection were minimal, loss of working days and cost of therapy were less in aspiration and sclerotherapy. While there was no recurrence in hydrocelectomy, 34.6% patients had recurrence after initial sclerotherapy and there was no improvement in them even after repeat aspiration and sclerotherapy. More patients were satisfied with open hydrocelectomy than aspiration and sclerotherapy and the major cause of dissatisfaction after aspiration and sclerotherapy was recurrence of swelling.

Our patients presented at an earlier age (median 33 years) than reported in western population.[2,11] The reasons could be earlier onset of the disease or only young patients are interested in seeking medical advice perhaps due to fertility worries.

In our study, 25/30 (83.3%) patients had scrotal pain at 48 h of hydrocelectomy which is similar to the finding of Shan and coworkers, where 73.5% patients had postoperative pain.[6] Twenty-one of 30 (70%) patients complained of pain after 48 h of sclerosant instillation which is comparable to Daehlin and coworkers observation where 18/22 (81.8%) patients had pain at one day after instillation of tetracycline.[4] However, Rencken and colleagues using a combination of sodium tetradecyl sulphate and rolitetracycline found pain only in 29% of the patients which is much lower than in our study.[12] This may be because of variation in tools used for assessing pain. Fuse and colleagues have proposed addition of lignocaine to sclerosant to avoid pain. However, two-third of our patients had pain in spite of using the mixture of sclerosant and lignocaine. An injection with local anesthetic into the cord before the treatment is probably a better option to decrease sclerosant associated pain.[13] The incidence of fever in our patients after aspiration and sclerotherapy is 6.5% which is comparable to the findings of Fracchia and coworkers who reported fever in 3/47 (6%) patients after sclerotherapy with the same agent.[11] The cause of fever is attributed to inflammatory reaction in the emptied tunica sac and we used anti-inflammatory agent only on demand. The mean loss of working days in our patients was 1.13 after sclerotherapy which is comparable to the report of Roosen and coworkers where 19 of 20 (95%) patients resumed normal activity within 24 h of therapy.[9] Fracchia and coworkers have reported that 94% patients resumed normal activity within 72 h of the sclerotherapy.[11] We found that the loss of working days in hydrocelectomy was seven times more than in sclerotherapy.

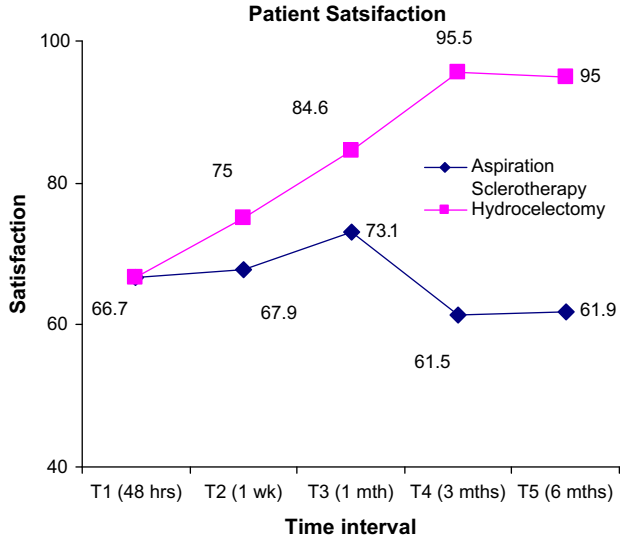

Fig. 1. Comparing satisfied patient in aspiration-sclerotherapy and hydrocelectomy group.

We found that the total cost of hydrocelectomy was three times more than sclerotherapy. But, this difference in the cost involved is three times less than in the west, which may be because of less operation cost, cheaper sutures and drugs in our hospital.[2,11]

In our study, 61.9% of patients had no recurrence after the single injection which is comparable to the reported cure rate of 64% by Rencken and coworkers,[12] but much less than 75%–88% success rate of other studies.[2,14] However, the comparison has to be made with caution as the definition of terms like 'success' and 'cure' are author dependent and variable. All of our patients undergoing repeat aspiration and sclerotherapy developed recurrence, supporting the observation that only a marginal improvement is achieved on success rate by repeating the treatment session.[2,11] However, there are also condictory reports of improvement in success rates by 32–44% with multiple sessions of aspiration and sclerotherapy.[12,15]

We have used more concentrated and smaller volume of sclerosing solution as suggested by Beiko and coworkers, but the success rate has not improved.[2] It has been reported that larger hydrocele has a greater chance of recurrence after initial sclerotherapy.[15] However; we found no significant difference in the median amount of fluid, duration of symptoms in patients with and without recurrence of hydrocele ($p = 0.54$) (Table 4).

In our study, 16/22 (62%) patients were satisfied with aspiration and sclerotherapy which is comparable to the of other reports.[2,11] It is interesting to find Stattin and coworkers have report of high satisfaction rate (95%) with aspiration and sclerotherapy with the same agent.[13] It is noteworthy that only one patient of hydrocelectomy who had developed haematocele and later pyocele was unsatisfied with the therapy. Beiko and coworkers have also reported high satisfaction rate (88%) with hydrocelectomy.[2]

We feel that inadequate sessions of repeat aspiration, shorter time interval between the initial and repeat aspirations, dilution of the sclerosing agent, subclinical filarial infection and inadequate temperature maintenance during storage of sclerosing agent may have resulted in lower success rate with sclerotherapy in our patients. However, this needs to be explored.

5. Conclusion

Even though the postoperative complications, morbidity and total expenditure were less; the recurrence rate and the patient satisfaction were not desirable in aspiration and sclerotherapy. Therefore, aspiration and sclerotherapy can be considered as an alternative option where resources for surgery are limited and hydrocelectomy should remain as the gold standard modality for the treatment of hydrocele.

Conflicts of interest
None declared.

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Ethical approval
Ethical approval was given by ethical committee of B.P. Koirala Institute of Health Sciences.

Author's contribution

Khaniya S. designed the study, drafted the manuscript and carried out literature search.

Koirala R. helped in literature search and manuscript drafting.

Regmi R. helped in statistical analysis.

Adhikary S, and Agrawal CS made critical revision and supervision.

All authors approved the final version of the manuscript.

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