Sclerotherapy for hydrocele revisited: a prospective randomised study

M. S. Agrawal · H. Yadav · A. Upadhyay · R. Jaiman · J. Singhal · A. K. Singh

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Abstract

Purpose A prospective randomised trial to study the efficacy and safety of hydrocele sclerotherapy with phenol and polidocanol.

Methods Eighty-six patients with unilateral primary vaginal hydroceles were randomised into three groups: group 1 (phenol sclerotherapy) – 29 patients, group 2 (polidocanol sclerotherapy) – 29 patients and group 3 (operative treatment) – 28 patients. Sclerotherapy was performed on outpatient basis using either 5–10 ml of 5% phenol or 2–4 ml of 1% polidocanol, while patients in group 3 underwent surgical repair of hydrocele (Jaboulay's procedure). Statistical analysis was performed using ANOVA.

Results The cure rates in group 1, 2 and 3 were 96.5%, 51.7% and 100%, respectively. The pain scores (visual analogue scale) in group 1, 2 and 3 at 1 week and 1 month were 14.5 and 1.8; 10.1 and 1.3; 64.0 and 10.6, respectively. There was significant difference among the three groups in mean hospital stay (1.8, 1.5 and 9.7 hours, respectively) and time to work resumption (1.3, 1.1 and 12.7 days, respectively). Statistically significant differences in pain scores and complications were observed between sclerotherapy and operative groups.

Conclusion Five percent phenol is a better sclerosant than 1% polidocanol and is as efficacious as operative treatment, with lesser morbidity and similar safety profile.

Keywords Hydrocele · Sclerotherapy · Phenol · Polidocanol

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 hydroceles. However, it is traumatic, painful and associated with high morbidity and prolonged convalescence. Sclerotherapy for hydroceles has grown in popularity as it is a safe, effective and economical outpatient therapy. The cure rate with various sclerosants reported in literature varies from 53% to 98% [1, 2].

We performed a prospective randomised study comparing the efficacy and safety of sclerotherapy for hydrocele (using 5% phenol and 1% polidocanol) with operative treatment.

Patient and methods

The study was carried out on 86 patients with unilateral hydroceles who were randomised into three groups: group 1 (phenol sclerotherapy) – 29 patients, group 2 (polidocanol sclerotherapy) – 29 patients and group 3 (operative treatment) – 28 patients. All cases of primary vaginal hydrocele were included in the study. Exclusion criteria were secondary hydrocele (secondary to trauma, malignancy or infection), communicating hydrocele, children < 12 years of age, and history of previous intervention (either sclerotherapy or surgery).

M. S. Agrawal · H. Yadav · A. Upadhyay · R. Jaiman · J. Singhal ·
A. K. Singh
Department of Surgery,
S. N. Medical College,
Agra, India

M. S. Agrawal (✉)
E-mail: dr.madhu.agra@gmail.com

Sclerotherapy was performed on outpatient basis. The patient was placed supine and painting with povidone iodine solution and draping was done. The puncture site was identified by transillumination of the scrotum to avoid trauma to the testis, followed by infiltration of skin and subcutaneous tissue with 2% lignocaine using a 24 gauge needle and 5 ml syringe. Scrotal puncture was done with an 18 gauge intravenous canula, which was connected to the intravenous line. Hydrocele fluid was drained by gravity and collected in a graduated container. Scrotum was manipulated to complete the emptying of the hydrocele. A sample of the fluid was subjected to cytological analysis. This was followed by injection of 5–10 ml of 5% aqueous phenol or 2–4 ml of 1% polidocanol. The respective volumes were selected on the basis of the studies of Shan et al and Sigurdsson et al for phenol and polidocanol, respectively [3, 4]. In none of the cases a second injection of the sclerosant was given.

The patients in the operative treatment group were treated under local anaesthesia with 2% lignocaine. The procedure was performed on a day care basis by eversion of sac (Jaboulay's procedure).

Patients were clinically reassessed at 1 week, 1 month, 3 months and 6 months after therapy, and earlier if any complication occurred. They were interviewed and examined in terms of post-treatment pain (recorded on the visual analogue scale at 1 week and 1 month), recurrence, complications (oedema, haematoma, wound infection), hospital stay and time to resumption of work. The hydroceles were considered as cured when they no longer had fluid and

transillumination on clinical examination. Transillumination persisting at 3 months follow up was taken as evidence of failure. One way Analysis of Variance (ANOVA) was applied to compare the three groups.

Results

The mean age of the patients in this study was 45.0 ± 13.8 years. The mean maximum diameter of the scrotal swelling was 123.0 ± 36.5 millimetres. The mean volume of the hydrocele studied was 212.9 ± 106.5 ml. The mean age, maximum diameter of the scrotal swelling and volume of hydrocele were comparable in three groups (Fig. 1).

The cure rates in group 1 (phenol sclerotherapy), group 2 (polidocanol sclerotherapy) and group 3 (operative treatment) were 96.5% (28/29), 51.7% (15/29) and 100.0% (28/28), respectively (Fig. 2). The observed cure rates in group 1 (96.5%) and group 3 (100.0%) were significantly more in comparison to group 2 (51.7%), the difference being extremely significant ($p < 0.001$). However, the difference in the cure rates between group 1 and group 3 was not statistically significant ($p > 0.05$).

Pain scores (analysed on the visual analogue scale in mm) at 1 week and 1 month were significantly higher ($p < 0.001$) in group 3 (operative treatment) as compared to both the sclerotherapy groups (Fig. 3). However, the difference in the pain scores between group 1 (phenol sclerotherapy) and group 2 (polidocanol sclerotherapy) was not statistically significant ($p > 0.05$).

Fig. 1 Patient characteristics

Fig. 2 Cure rates

Fig. 3 Pain scores at 1 week and 1 month

Similarly, the mean durations of hospital stay and time to work resumption were significantly more ($p < 0.001$) in group 3 (operative treatment) as compared to group 1 and group 2 (Fig. 4). However, the difference in these two parameters between the sclerotherapy groups was not statistically significant ($p > 0.05$).

In both group 1 and 2, oedema and haematoma were observed in 6.9% (2/29) of the patients and none of the patients developed wound infection (Fig. 5). In group 3 (operative treatment) 35.7% (10/28) developed oedema and haematoma, while 7.1% (2/28) had wound infection (Fig. 5). These observations revealed a significantly higher

Fig. 4 Duration of hospital stay and time to work resumption

Fig. 5 Complications

incidence of complications ($p < 0.05$) in group 3 as compared to the other two groups.

Discussion

In recent years, there has been a paradigm shift towards minimally invasive approaches for the treatment of increas-

ing number of diseases. 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. Aspiration with sclerotherapy represents a minimally invasive approach to the treatment of hydrocele.

In the present study the mean hydrocele volume (212.9 ml) is comparable to the mean volume reported in other

studies [3, 5–7]. The volume of phenol instilled by us is in accordance with the studies of Shan et al in which volume of phenol instilled was proportional to the volume of the hydrocele [3]. In their study, the phenol instilled was 2.5% in aqueous medium and the volume instilled was 10% of the volume of the drained hydrocele when < 400 ml, and 5% of drained volume when it exceeded 400 ml. However, we did not exceed the upper limit of the sclerosant volume because not only the concentration of phenol used in our study was high but we also aimed to achieve sclerosis resulting from close apposition of visceral and parietal layers of the tunica vaginalis, which would not have been possible by voluminous sclerosant between the two. The volume of polidocanol used ranged from 2 to 4 ml based on the studies of Sigurdsson et al. [4]. Here too, we did not exceed the upper limit of the volume of the sclerosant due to the aforesaid philosophy.

We achieved an excellent cure rate of 96.5% using a single session of sclerotherapy with 5% phenol. This is in accordance with majority of the published studies, where the success rates with phenol have been consistently above 90% (although these results were achieved with lesser concentrations and multiple sclerotherapy sessions) [3, 8, 9].

We have used 5% phenol for sclerotherapy, as used by East et al. [10], since our previous experience too had shown superior results with a 5% concentration over more conventional 2.5–3% concentrations used in previous studies [3, 8, 9]. Other sclerosants have also shown good results, however with multiple sessions of sclerotherapy: studies by Tammela et al using 5% ethanolamine oleate sclerotherapy (68% cure rate with a single session and 98% with multiple sessions) [2]; Onu using tetracycline (55.5% patients treated with a single injection and an overall success rate of 98%) [11]; and Rencken et al using 3% sodium tetradecyl sulphate and 3.5% rolitetracycline (64% patients cured after a single sclerosant injection and 96% overall cure rate) [12]. Five percent phenol, however, scores over all these agents as only a single sclerotherapy session accounted for our results. In the light of these findings, 5% phenol should definitely be viewed as a viable first-line therapeutic option in the management of hydrocele.

Our result using a single session of polidocanol sclerotherapy (51.7% success) is consistent with the cure rate observed by Daehlin et al (53%) [1]. However, Sigurdsson et al. and Fuse et al. have reported higher success rates (67% and 73%, respectively) with a single session of polidocanol sclerotherapy [4, 5]. In group 3 (operative treatment), we were able to achieve a 100% cure rate which is similar to the previously reported results [3, 13, 14].

In our study, the use of a higher concentration of phenol did not add to the risk of complications, with oedema and haematoma noted in only 6.9% of our patients. Similarly, 6.9% patients developed oedema and haematoma in group 2 (polidocanol sclerotherapy) and these findings are comparable to those observed by Sigurdsson et al. [4].

Phenol sclerotherapy was found to be somewhat more painful than polidocanol, possibly because of the corrosive nature of phenol. Polidocanol has some anaesthetic property, which is why a lower incidence of pain was noted in this group [3, 5, 15].

Though operative treatment came with 100% cure, it resulted in a significantly higher incidence of postoperative pain, complications and period of convalescence.

Another limitation of our study was the use of a fixed concentration of phenol for all cases. A comparison between different concentrations of phenol may be the subject of a larger follow up study to establish the optimum dose of phenol more conclusively.

Conclusion

Operative treatment for hydrocele is the gold standard against which all other forms of treatment should be compared. Though, overall cure rate with operation for hydrocele is higher, but looking at the comparable efficacy, safety profile and relative ease of administration, aspiration and sclerotherapy can be used as a first-line option in the treatment of hydroceles. Our study suggests that sclerotherapy with a more conventional agent like phenol is more effective than newer agents like polidocanol, and the results are comparable with operative treatment with significantly less morbidity and hospital stay.

Conflict of interest The authors do not have any disclosable interest

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