ORIGINAL RESEARCH

Povidone Iodine Sclerotherapy for Idiopathic Hydroceles: An Inexpensive, Safe, Effective and Minimally-Invasive Alternative

Marlo Vir C. Batucan, MD and Enrique C. Tenazas, MD, FPUA

Department of Urology, Vicente Sotto Memorial Medical Center, Cebu City

Hydrocelectomy remains the most common treatment modality in the management of idiopathic hydrocoele. Aspiration and Sclerotherapy for hydroceles has gained increasing acceptance owing to its less-invasiveness and improved treatment outcomes almost par with surgery.

Objective: This study demonstrated the use of 10% Povidone Iodine for sclerotherapy as a safe and effective treatment option in the management of idiopathic hydroceles in adults.

Methods: This study was quasi-experimental in nature. Non-septated idiopathic hydroceles diagnosed at Vicente Sotto Memorial Medical Center Uro- OPD from October 1, 2014 - September 30, 2015, underwent hydrocele aspiration and sclerotherapy with 10% Povidone Iodine. Follow-up data were collected at 1, 4 and 8 weeks respectively. Patients with noted decrease in scrotal size, improved physical symptoms and minimal persistence (<30cc) of hydrocele fluid per scrotal ultrasound at 8 weeks were regarded as successful cases.

Results: A total of 20 patients presenting with 24 hydroceles underwent Aspiration and Scleroptherapy with Povidone Iodine. Twenty-one (87.5%) were successfully treated after a single procedure, and 3 (12.5%) eventually had hydrocelectomy. Mean aspirate volume of the success group is 249 cc versus 710 cc in the failure group. All of the patients reported no experience of pain/ discomfort during and immediately after the procedure. One patient followed up with a hematoma which spontaneously resolved at the 4th day post procedure.

Conclusion: The use of 10% Povidone Iodine is effective and safe sclerosing agent for aspiration and sclerotherapy of Idiopathic hydrocoeles. We report a success rate of 87% thus, using Povidone Iodine sclerotherapy for idiopathic hydroceles can be a practical, effective, safe and minimally invasive treatment alternative.

Key words: Povidone Iodine, Sclerotherapy, Hydrocele

Introduction

Scrotal enlargement is the most common VSMMC Urology-OPD consultation for scrotal abnormalities. Hydrocele is the most common cause of scrotal swelling in men that causes physical, psychological, social and economic distress. Men are often ashamed of the condition

and more often, seek consult only after an associated discomfort, pain, interference with daily activities and sexual intercourse.

Surgery is the conventional treatment of idiopathic hydrocele.[1] Hydrocelectomy is performed by excision and subsequent eversion of the tunica vaginalis sac. This procedure remains the most popular surgical method. However, like other invasive modalities, it is associated with the inconvenience and the cost of hospitalization, complications such as prolonged pain, hematoma formation, infection, and injury to the scrotal contents including the testicle, epididymis and vas deferens.[2] Conservative methods include observation, aspiration, and sclerotherapy. Conventionally, aspiration and sclerotherapy has been indicated for patients who are poor surgical candidates and unwilling to undergo surgery.[3] More recently, aspiration and sclerotherapy as treatment option for hydroceles is gaining popularity as it is less invasive, safe and can be performed as an out-patient procedure.

Over-all success rate for aspiration and sclerotherapy was 76% compared to 88% with surgery but with only a complication rate of 8% for aspiration and sclerotherapy versus 40% that of the surgery group.[4] Moreover, aspiration and sclerotherapy is a better treatment option than with aspiration alone. Various studies have been published about treatment outcomes with aspiration and sclerotherapy, but these studies showed inconsistencies in outcomes because of lack of uniformity of methods and the sclerosing agents used.[5] Different sclerosing agents are now widely used in the treatment of hydrocoele including: 99.5% alcohol6, phenol[7], ethanolamine oleate[8,9], polidocanol[10,11], sodium tetradcyl sulfate[4,12], tetracycline[13] and doxycycline. More recently Franci et al in 2013 established an increased success rate of aspiration and sclerotherapy to 84% using doxycycline.[14]

Povidone Iodine is a stable chemical complex polyvinylpyrrolidone (PVP) and elemental iodine. It has been broadly used for the prevention and treatment of skin infections, and the treatment of wounds. Povidone Iodine is a topical antiseptic that has been reported as an effective and safe sclerosing agent for pleurodesis for malignant pleural effusion in 2 series published.[15,16] For this purpose, Povidone Iodine is equally effective and safe as talc, and may be preferred because of easy availability and low cost.[18] Povidone Iodine has the advantage of being readily available, inexpensive and less painful when administered compared to other agents.

Currently, to the authors' knowledge, there are no published local or international studies on the use of Povidone Iodine as a sclerosing agent for aspiration and sclerotherapy in the treatment of idiopathic hydroceles.

In a tertiary government hospital setting where there is a limited number of surgical beds but with so many patients and a scenario where majority of the patients have limited financial resources; performing an outpatient procedure that offers comparable efficacy with surgery using a widely available, inexpensive and safe sclerosing agent is a promising alternative.

Materials and Methods

This quasi experimental study was, approved by the Institutional Ethics Board of Vicente Sotto Memorial Medical Center. All patients who were clinically diagnosed with idiopathic hydrocele at the VSMMC Uro-Out Patient Department from October 1, 2014 - September 30, 2015, aged 40-80 years old underwent evaluation by history, physical and genital examination. Scrotal ultrasound was likewise done to determine the nature of hydrocele and rule out the secondary causes of hydrocele such as hernia, malignancy, infection, etc. Exclusion criteria were presentation of multi-septated hydroceles by ultrasound, identifiable problems in the scrotum such as tumors, infection, hernia, history of recent trauma. Patients with known sensitivity to iodine, diagnosed with thyroid disease or those with anterior neck masses, known with CHF, liver cirrhosis, ascites/ peripheral edema were also excluded from the study. The sample size was computed using Power and Sample Size Program ver. 3.0.14 requiring 19 subjects/patients which was met for the duration of the study.

The patients were made aware of their condition, the available treatment options including surgery, outcomes, risks and benefits of aspiration and sclerotherapy were all discussed

prior to obtaining consent. The standardized technique of aspiration and sclerotherapy with Povidone Iodine was strictly adhered for all eligible patients and was performed by a single surgeon. The affected side of the hemi-scrotum was cleansed and prepped with Povidone Iodine and sterile eye sheet was draped. A unilateral spermatic cord block with 5cc of 2% lidociane was given. A gauge 16 IV cannula was inserted percutaneously on the anterior superior or lateral aspect of the scrotum. The plastic stillete was withdrawn noting a backflow of fluid and leaving the cannula in situ.

Aspiration of hydrocele fluid was commenced using a 50cc syringe and the amount of aspirate fluid was recorded. Ten milliliters of 10% Povidone Iodine (same brand name, source, manufacturing company) was administered via the IV cannula into the empty tunica vaginalis sac. The IV cannula was withdrawn. The patients were advised to massage the scrotum for at least 5 minutes to expose the lining of the sac to the sclerosing agent. Patients were given Ibuprofen 300mg to be taken at 8-hour intervals as needed for pain. No antibiotics were given. The patients followed up at 1, 4 and 8 weeks post procedure. The patients reported their outcomes using a non-validated questionnaire immediately after the procedure, resolution and recurrence of hydrocele.

A successful aspiration and sclerotherapy with Povidone Iodine in this study was defined as complete to minimal persistence of hydrocele (<30cc) with repeat ultrasound at 8 weeks post procedure and resolution of discomfort after a single procedure. Criteria for failure included recurrence of hydrocele (documented per UTZ >30cc at 8 weeks) or presentation for a re-aspiration and sclerotherapy or eventual hydrocelectomy.

Results

There were 20 patients who presented with 24 idiopathic, non-septated hydroceles between October 1, 2014 - September 30, 2015. Four of the 20 patients presented with bilateral hydroceles. The most common presentation for treatment was discomfort in 70% of patients, other reasons included cosmesis and perceived gradual increase of hydrocele size. Patients presented for consult/ treatments the average of 3.45 years after hydrocele was first noted.

N = 24	Success	Failure
Number of Hydroceles (%)	21 (87%)	3 (12.5%)
Mean Age (range)	59.2 years (45-76 years)	55.3 years (50-64 years)
Number of unilateralhydrocele	11	2
Number of bilateral hydrocele	3	1
Mean Aspirate Volume	249 cc	710 cc (540-1020 cc)

Of the 24 hydroceles, 87.5% (n=21) were reported as successful aspiration and sclerotherapy with Povidone Iodine after a single procedure and 3 (12.5%) were considered treatment failure. These 3 patients opted for hydrocelectomy after. The mean volume of aspirated hydrocele in the success group was 249.5cc versus 710 cc in the failure group with a range of 540-1020 cc volume of hydrocele fluid.

Over-all mean follow up for this study was 7.8 months and majority of none to mild discomfort during and after the procedure. None of the patients reported hematoma after the procedure and no infection was documented.

Discussion

Hydrocele is the most common cause of scrotal enlargement affecting 1% of adult men and usually seen at the age of >40 years old.[2] The pathophysiology of an acquired hydrocele is unclear but maybe from increased serous fluid secretion, lack of efferent lymphatics or failure of lymphatics in the mesothelial lining to reabsorb fluid.[5]

Aspiration is simply removing the fluid from the hydrocele sac. In a study by Yilmaz, et al. comparing hydrocele therapy with aspiration alone vs. aspiration with sclerotherapy, the hydrocele

recurred in all of the patients treated by aspiration alone.

Sclerotherapy is a necessary step after aspiration to create an inflammatory reaction and subsequent fibrosis that impedes the flow and accumulation of fluid into the hydrocele sac.[4] But what is an ideal sclerosing agent? According to Argawal, et al. an ideal sclerosing agent should have a high molecular weight and chemical polarity, low regional clearance, rapid systemic clearance , a steep-dose response curve and should well be tolerated with minimal or no side effects.[22]

This study was the first to use 10% Povidone Iodine as a sclerosing agent for aspiration and sclerotherapy of idiopathic, non-septated hydroceles. Povidone Iodine is gaining acceptance as a sclerosing agent in the management of pleural effusion regardless of etiology (malignant, non malignant) and is regarded as effective, safe, inexpensive and readily available.[17] It was also used a sclerosing agent in a published case report of sclerotherapy of a giant renal cyst in combination with doxycline which proved to be successful.[19] Similarly, Povidone Iodine has also been reported in sclerosis of pelvic lymphoceles.[20] Prior studies to support these were done by OlivaresTorres, et al. in 2002 and Gondazaneh, et al. in 2013. They have shown that admistration of Povidone Iodine does not affect thyroid function in adults.[15,17] Further, Yeginsu, et al. in 2007 reported that in contrast to infants, normal subjects without pre existing thyroid disease are able to tolerate systemic iodine uptake well without any physiological disturbance. The precise mode of action of Povidone Iodine as sclerosing agent remains unclear but it may be related to its low pH (2.97) or to the strong oxidative and cytotoxic properties of iodine which induce a potent inflammatory response in the wall of any fluid containing structure.[15,21] Povidone Iodine also has anti-exudative properties which may be related to the chelation of proteins.[22]

In a related study done by Beiko, et al. with almost comparable number of subjects (n=25), it was reported an 84% success rate of hydrocelectomy cases versus 60% success rate of aspiration and sclerotherapy with tetradecyl-sulfate.[4] Notable in this study is that 40% of patients who underwent successful hydrocelectomy experienced post op complications such as hematoma, edema, infection, and cellulitis. In the present study with aspiration and sclerotherapy with Povidone Iodine, all patients reported no pain during the conduct and immediately after the procedure. Only 1 of the 24 (4%) cases had a notable minimal hematoma which spontaneously resolved on the 4th day post procedure.

A study of Levine, et al. in 1998 using Tetracycline for the aspiration and sclerotherapy of hydroceles reported a success rate of 75% (21of 28 patients).[13] A more recent study of Francis et al. in 2013 reported an increased success rate to 84% using doxycycline as sclerosing agent.[14] This success rate is similar to hydrocelectomy. This study, as the first to use Povidone Iondine as a sclerosing agent for aspiration and sclerotherapy of hydroceles reported a success rate of 88%. The results showed that the use of Povidone Iodine as sclerosing agent for hydroceles has a comparable outcome with surgery/ hydrocelectomy without the associated complications of surgery and anesthesia, and avoiding the cost of hospitalization since it can be performed as an outpatient procedure.

Appendix A lists a table of published studies with aspiration and sclerotherapy with various agents and their reported success rates.

This study reported 3 cases out of 24 had recurrence and eventually underwent hydrocelectomy per patients' choice. The mean volume of aspirate from this gourp is 710cc (with range 540-1020). These findings affirmed that of Levine et al. that identified aspirate volume as a predictor of treatment failure.[13] This study recommends then that hydrocele size of more than 500cc will be most likely to benefit with surgery (hydrocelectomy).

Further, this study highlights the practicability of the procedure and the agent used. In comparison with other agents as medical grade talc, tetracycline (veterinary grade since medical grade powder form is not available), doxycycline--- Povidone Iodine is the most inexpensive and widely available since it is being marketed as antiseptic cleanser/paint. This out-patient

procedure lasts 10-15 minutes. The procedural cost of aspiration and sclerotherapy with Povidone Iodine is around 300-500 pesos/patient versus 5,000-10000 pesos/patient that will be spent with hydrocelectomy excluding the doctor and anesthesiologist's fees.

The limitations of this study included its quasi-experimental non-controlled study design, the limited sample size, and the non-validated investigator generated questionnaire. This study can also be recommended to use visual acuity scoring (VAS) for more measurable assessment of pain as an advantage of this procedure compared to surgery. This study as a pilot study may warrant further studies or controlled trials to establish and strengthen is finding as a possible non-surgical and out-patient alternative in the management of idiopathic hydroceles.

Conclusion

The use of 10% Povidone Iodine is an effective and safe sclerosing agent for aspiration and sclerotherapy of idiopathic hydroceles. Current findings demonstrate success rates similar to the use of other sclerosing agents and with hydrocelectomy in the literatres; without the complications, inconvenience and cost of hospitalization.

References

1. Lord PH. Abloodless operation for the radical cure of idiopathic hydrocele. Br J Surg 1964; 51: 914.

2. Swartz MA, Morgan TM, Krieger JN. Complications of scrotal surgery for benign conditions. Urology 2007; 69: 616.

3. Moloney GE. Comparison of results of treatment of hydrocele and epididymal cysts by surgery and injection. Br Med J 1975; 3: 478.

4. Beiko DT, Kim D, Morales A: Aspiration and sclerotherapy versus hydrocoelectomy for treatment of hydrocoeles. Urology 2003; 61: 708.

5. Khaniya S, Agwal CS, Koirala R, Regmi R, Adhikary S Comparison of aspiration sclerotherapy with hydrocoelectomy in the management of hydrocele: a prospective randomized study. Int J Surg 7 (4): 392-5.

6. Shan CJ, Lucon AM, Pagani R, et al. Sclerotherapy of hydroceles and spermatoceles with alcohol: results and effects on semen analysis. Int Braz J Urol 2011; 37: 307.

7. Savion M, Wolloch Y, Savir A. Phenol sclerotherapy for hydrocele; a study in 55 patients. J Urol 1989; 142: 1500-1.

8. Hellstorm PA, Tamella TL, Koatturim M, Lukkarinen O: Ethanolamine oleate as sclerosant for testicular and epididymal cysts. Br J of Urol 1988; 62: 445-8.

9. Tamella TL, Hellstorm PA, Matilla SL et al. Etholamine oleate scerotherapy for hydroceles and spermatoceles; a survery of 158 patients with ultrasound follow-up. J urol 1992; 147: 1551.

10. Jahnson S, Sandblom D, Holmag S. A randomized trail comparing 2 doses of polidocanol sclerotherapy for hydrocele and spermatocele. J Urol 2011; 186: 1319.

11. Sallami S, Binous MY, Ben Rhouma S et al. Sclerotherapy of idiopathic hydrocele with poliocanol: a study of 190 cases. Tunis Med 2011; 89: 440.

12. Stattin P, Karlberg L, Damber JE. Long term outcome of patients treated for hydrocele with sclerosing agent sodium tetradecyl sulphate. Scand J Nephrol 1996; 30: 109-3.

13. Levine LA and DeWolf WC. Aspiration and Tetracycline Sclerotherapy of Hydroceles. J Urol 1988; 139: 959.

14. Francis JJ, Levine L. Aspiration and Sclerotherapy: a non-surgical treatment option for hydroceles. J Urol 2013; 189: 1725-9.

15. Olivares-Torres CA, Laniado-Laborin R, Chavez-Garcia C, et al. Iodopovidone pleurodesis for recurrent pleural effusion. Chest 2002; 122: 581-3.

16. Yeginsu A, Karamustafaoglu A, Ozugurlu F, et al. Iodopovidone pleurodesis does not affect thyroid function in normal adults. Interact Cardiovasc Thorac Surg 2007; 6: 563-4.

17. Godazandeh G, Qasemi N, Saghafi M et al. Plerodesis with povidone iodine , as safe and effective procedure in management of patients with malignant pleural effusion. J Thorac Dis 2013; 5(2): 141-4.

18. Das SK, Saha SK, Das A, Halder AK, Banerjee SN, Chakraborty M. A study of comparison of efficacy and safety of talc and povidone iodine for pleurodesis of malignant pleural effusions. J Indian Med Assoc 2008; 106 (9): 589-90, 592.

19. Peyromaure M, Debre B, Flam TA. Sclerotherapy of giant renal cyst with povidone iodine. J Urol 2002; 168: 2525.

20. Cohan RH, Saeed M, Schwab SJ, et al. Povidone iodine sclerosis of pelvic lymphoceles: A prospective study. Urol Radiol 1988; 10: 203-6.

21. Brissaud O, Desfrere L, Mohsen R, et al. Congenital idiopathic chylothorax in neonates; chemical pleurodesis with povidone iodine. Arch Dis Child fetal Neonatal 2003; 88: F531-3.

22. Agarwal R, Aggarwal AN, Gupta D, et al. Efficacy and safety of iodopovidone in chemical pleurodesis: A meta-analysis of observational studies. J Res Med 2006; 100: 2043-7.

Appendix A: Comparison of hydrocele aspiration and sclerotherapy single procedure success rates from published reports using various sclerosing agents.

Authors	Year of Publication	Number of Patients	Agent Used	Mean Follow Up Time (Months)	Single Procedure Success Rate
Shan, et al.	2011	84	99.5% Alcohol	43	75%
Tammela, et al.	1992	102	5% Ethanolamine Oleate	43	68%
Jahnson, et al.	2011	224	Polidocanol	3	54%
Sallami, et al.	2011	190	Polidocanol	19	62%
Daehlin, et al.	1997	17	Polidocanol	9	53%
Sigurdsson, et al.	1995	63	Polidocanol	14	67%
Beiko, et al.	2003	25	3% Sodium Tetradecylsulfate	8.9	60%
Rencken, et al.	1990	55	3% Sodium Tetradecylsulfate	13	64%
Daehlin, et al.	1997	20	Tetracycline	9	85%
Shokeir, et al.	1994	21	Tetracycline	45	57%
Miskowiak and Christensen	1988	27	Tetracycline	6	85%
Levine and DeWolf	1988	28	Tetracycline	15	75%
Bullock and Thurston	1987	37	Tetracycline	9	84%
Badenoch, et al.	1987	15	Tetracycline	6	33%
Francis, et al.	2012	29	Doxycycline	19	84%
Current Study	2015	24	Povidone Iodine	9.3	87%