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RESEARCH ARTICLE

SAFETY AND EFFICACY OF FLUOROSCOPIC GUIDED INSTILLATION OF POVIDONE IODINE WITH CONTRAST AGENT FOR TREATMENT OF CHYLURIA

***Prakash, J.V.S., Dhanasekaran, D. and Barani, S.**

Institute of Urology, MMC, Chennai

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ABSTRACT

Objectives: To evaluate the safety and efficacy of fluoroscopic guided instillation of povidone iodine with contrast agent. To compare the results obtained with that of povidone iodine instillation without using fluoroscopy.

Methods: A prospective study was done in Institute of Urology, MMC, Chennai between February 2015 to February 2016. 43 patients were included in the study after conforming chyluria. Patients were randomly divided into 2 groups- Study group including 20 patients and Control group including 23 patients. Study group was treated with fluoroscopic guided instillation of povidone iodine with contrast where as in Control group, fluoroscopy was not used.Single instillation of 10 ml of 0.2% povidone iodine were given in both groups.Post procedure ether test and cystoscopy was done every 3 weeks for a total duration of 3 months. If symptoms of chyluria recurred, instillation was repeated.

Results: Majority of participants in study group were affected in right side (55%), while in control group majority were affected in left side (56.5%). This difference was not statistically significant. On comparing frequency of sittings needed, only 15% patients in study group needed more than one sitting versus 56.5% in control group, which was statistically significant. 15 % of patients in study groups experienced any complication versus 13% in control group. The difference was not statistically significant.

Conclusion: Use of fluoroscopy guided instillation of povidone iodine is safe and efficacious. Single instillation is as efficacious as multiple instillation regimens.

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INTRODUCTION

Chyluria is a common condition occurring in rural and low socio-economic population of the tropical countries where sanitation is poor and prevalence of filariasis is high. By definition it is the passage of milky white urine containing chyle. Components of chyle are colloidal fat, albumin and fibrin in various ratio. It is most commonly caused by infestation due to parasite wuchereria bancrofti. It is called as parasitic, primary or tropical chyluria. Chyluria can be simply confirmed by the bed side test due to thes olubility of colloidal fat in ether. Various treatment modalities have evolved in the past for the management of chyluria starting from dietary restriction of fat to major surgeries like lymphovenous disconnection. Before invasive surgeries, sclerotherapy is done for themanagement of chyluria with high success rate.

****Corresponding author: Prakash, J.V.S***
Institute of Urology, MMC, Chennai

Various agents have been used in the past for sclerotherapy, among those silver nitrate enjoyed the vast majority of cases of sclerotherapy instillation. However it is associated with technical difficulties in the preparation of fresh silvernitrate solution and high morbidities like ureteric obstruction and acutetubular necrosis. Nowadays povidone iodine has become the sclerosing agentof choice. In this study we aim to study the safety and efficacy of fluoroscopic guided instillation of povidone iodine with contrast agent. We will also compare the results obtained with that of povidone iodine instillation without fluoroscopic guidance. We will also aim to find out the efficacy of first instillation of povidone iodine.

MATERIALS AND METHODS

This study was done prospectively at a tertiary care institute for a period of from February 2015 to February2016. Ethical clearance was taken from the Institute Ethics Committee prior to the start of the study. Patients presenting to outpatient

department with complaints of passage milky white urine were screened with history taking, physical examination, ether test, urine triglycerides, urine routine, blood routine, ultrasound kub, x-ray kub, contrast enhanced ct-kub and a diagnostic cystos copy. After excluding patients who cannot tolerate lithotomy position, patients allergic to povidone iodine or contrast media and patients with severe co-morbid illness a total of 43 patients confirmed to have chyluria were selected and included in the study after taking informed consent. Patients were randomly divided into 2 groups- Study group including 20 patients and Control group including 23 patients. Study group included those patients to be treated with fluoroscopic guided instillation of povidone iodine with contrast media while Control group included those who were to be treated with povidone iodine without using fluoroscopy.

Procedure

It was done as an outpatient procedure after evaluation and confirming the presence of chyluria. All patients were put on oralantibiotics preoperatively one day prior and four days post operatively. All patients were advised to take 50gms of butter or high fat diet on the2-3 hours prior to procedure to improve the chylous efflux. Under localanaesthesia, strict aseptic precautions and in lithotomy position all patients were subjected to standard cystoscopy. Laterality of chylous efflux was confirmed and with bulb tip catheter, selected ureter was engaged snuggly.

Study Group

Patients were treated with fluoroscopic guided instillation of povidone iodine with contrast agent assclerosant. Sclerosing solution was prepared by adding 2ml contrast iohexol, 1ml 5% povidone iodine and23 ml distilled water to achieve a final concentration of around 0.2%. 10 ml of solution was injected via bulb tipureteric catheter till the complete visualization of all the calyces with mildblunting of fornices was seen.

Control Group

Patients were treated with instillation of povidone iodine alone without fluoroscopy. Formal cystoscopy was performed to identify the side of effluxand 10 ml of 0.2%povidone iodine injected into selected side via bulb tip ureteric catheter. Single instillation of 10 ml of 0.2% povidone iodine were given in both groups.Post procedure ether test and cystoscopy was done every 3 weeks for a total duration of 3 months. If symptoms of chyluria recurred, instillation was repeated.

RESULTS

Around 43 patients with chyluria were included in the study, among them 20 patients were treated with fluoroscopic guided instillation of povidone iodine and contrast and 23 patients were treated with instillation of povidone iodine alone without fluoroscopy. Age distribution of participants shows that the age ranges between31 to 60 with the mean age as 44years and SD as 8.0years.For analysis purpose the age in years were classified into three categorical groups- 31-40 years, 41-50 years and 51-60 years, (Table 1). The age distribution show majority of the participants in both groups belonged to 31-40 age group (39.5%). The comparison of age distribution between the study group and control group showed no statistical significant difference (p-value >0.05). Hence both groups are comparable, (Table 2). Among the 43 study participants around 23 were males and 20 were females. The gender distribution shows the majority of participants in the study group were male (65%) and in control group were female (56.5%) but this difference was not statistically significant (p-value=0.158). Hence the both groups are comparable (Table 3). Based on the affected side the participants were classified into three groups right side, left side and bilateral. Majority of participants were affected in left side (48%) followed by right side (44%). Around 7% of study participants were affected on both sides.

Table 1. Comparison of age distribution

Sl. no	Groups	Frequency	Mean Age (years)	SD	t-value	p-value
1	Study Group	20	44.10	8.188	-0.057	0.933
2	Control Group	23	43.96	8.188		

Table 2. Comparison of age-group distribution

Sl. no	Age Group	Study Group n (%)	Control Group n (%)	Total n (%)	p-value
1	31-40 years	8(40)	9(39.1)	17(39.5)	0.726
2	41-60 years	6(30)	9(39.1)	15(34.9)	
3	51-60 years	6(30)	5(21.7)	11(25.6)	
	Total	20(100)	26(100)	43(100)	

Table 3. Comparison of gender distribution

Sl.no	Gender	Study Group n (%)	Control Group n (%)	Total n (%)	p-value
1	male	13(65)	10(43.5)	23(53.5)	0.158
2	female	7(35)	13(56.5)	20(46.5)	
	total	20(100)	26(100)	43(100)	

Table 4 shows majority of participants in study group were affected in right side (55%), while in control group majority of participants were affected in left side (56.5%). This difference was not statistically significant (p-value= 0.407). Hence the participants in both groups were comparable. Frequency of sittings needed is an important outcome factor in the study. The frequency of sittings ranged between 1 to 3 sitting with an average sitting of 1.4 and SD of 0.58. Table-5 shows the comparison of number of sittings needed for treatment between the study and control group. Only15% of patients treated with fluoroscopic guided instillation of povidone iodine needed more than one sitting for treatment. Compared to that more than half of the participants in control group (56.5%) needed more than one sitting. When we apply chi-square this difference is statistically significant (p-valve<0.05).To measure the association relative risk was used. The relative risk (RR) for needing more than one sitting among the control group is 3.76.

Since it is a late manifestation of filarias is it is not possible to demonstrate microfilaria when adult worms are burnt out. Confirmation of chyluria by ether test alone has low sensitivity as demonstrated by Goel *et al*. (2004). He reported that only 31% of cases of chyluriais positive for ether test and confirmed by the demonstration of lymphocytes in the urinary sediments later. Methylene blue test will demonstrate presence of lymphocytes in urine deposits. In our study we routinely advised the patient to take fatty meal like 50gms of butter before examination of urine for chyle by ether test. Almost all patients were positive for ether test. Yamuchi *et al*. (1945). reported that post prandial urinary triglyceride measurements were 100% sensitive and 100% specific for chyluria. Chyluria is a distressing disease causing morbidity to the patient without life risk. Because of the nature of the disease it needs less invasive treatment in the form of cytoscopic guided instillation of sclerosant solutions into the renal pelvis without much complications.

Table 4. Comparison of affected side

Sl.no	Side involved	Study Group n (%)	Control Group n (%)	Total n(%)	x^2-value	p-value
1	Left	8(40)	13(56.5)	21(48.8)	1.797(2)	0.407
2	Right	11(55.5)	8(34.8)	19(44.2)		
3	Bilateral	1(5.0)	2(8.7)	3(7.0)		
	Total	20(100)	23(100)	43(100)		

Table 5. Comparison of frequency of sittings needed

Sl.no	Sittings	Study Group n (%)	Control Group n (%)	Total n(%)	p-value
1	One	17(85)	10(43.5)	27(62.8)	0.005
2	More than one	3(15)	13(56.5)	16(37.2)	
	Total	20(100)	23(100)	43(100)	

Table 6. Comparison of complications

Sl.no	Complications	Study Group n (%)	Control Group n (%)	Total n(%)	p-value
1	Nil	17(85)	20(87)	37(86)	0.853
2	Any one	3(15)	3(13)	6(14)	
	Total	20(100)	26(100)	43(100)	

This shows the need of more than one sitting among chyluria patients treated with instillation of povidone iodine alone is 3.76 times higher than patients treated with fluoroscopic guided instillation of povidone iodine. Among 43 participants around 6 patients had some complications like pain, fever. Table 6 shows the comparison of complications between the study and control group. 15% of patients treated with fluoroscopic guided instillation of povidone iodine and 13 % of patients treated with instillation of povidone iodine alone had anyone complication. This difference was statically not significant while applying chi-square test (p-value>0.05).

DISCUSSION

Primary chyluria is a tropical disease where filariasis is common. It usually presents decades after the initial infection by the microfilaria. After deposition of microfilaria onto the skin,it gets access to regional lymph nodes where develop into adult worms. They migrate to major lymph vessels and produce millions of microfilaria. These vessels can be obstructed and chyluria will be manifested. It is associated with frequent remissions and exacerbations spontaneously.

Silver nitrate enjoyed vast majority of cases sclerotherapic instillation for the management of chyluria in the past. Difficulties were encountered with the preparation of silver nitrate solution. They were

- Getting good quality silver nitrate salt,
- Need for preparation of fresh solution during each time of instillation,
- Need for sterilization after preparation of fresh solution,
- Difficulties in the preparation of precise concentration of solution.

It was also associated with serious side effects like

- Acute tubular necrosis,
- Acute interstitial nephritis,
- Acute papillary necrosis,
- Acute renal failure and death.

Because of its serious complications difficulties encountered in the preparation of fresh solution povidone iodine replaced the role of silver nitrate in the management of chyluria. Povidone

iodine is easily available, safe, non toxic, non irritant and more economical. It has less side effects and equally efficacious. It also has antimicrobial activities against bacteria, bacterial spores, fungi andvirus. In 1998 Shanmugam *et al.* (1998), first used povidone iodine 0.2% in the management of chyluria in our institute with 100% success rate. In his study he included five patients and followed up for 6 months. He used single instillation of povidone iodine. Even though the study size was small with small duration follow up the good results obtained encouraged other to follow up povidone iodine as sclerosant agent instead of silvernitrate. In 2004 Nandy *et al.* (2004) reported 83% success rate in the mean follow up period of twenty four months. He used 5% povidone iodine and 50%dextrose as a sclerosant. He instilled sclerosant twice daily for total ofthree days. In 2008 Sharma *et al.* (2008), reported 87% success rate in his 40 patients. He followed cases for twelve months. He used 76% urograffin, 5%povidone iodine and distilled water in the ratio of 1:1:3. He did single instillation under fluoroscopic guidance. He used bulb tip ureteric catheter and kept it in position for few minutes and adequacy of instillation is assessed by just blunting of calycealfornices. Repeat instillation were done six weeks later if chyluria persist or recurred with good success rate. In our study we instilled povidone iodine under fluoroscopy in 20patients with 85% success rate in three month follow up. Three patients were not cleared of chyluria who were treated successfully with repeat instillation. Control group in our study had more failure rate around 56%. It might be attributed to lack of assessment of precise volume of sclerosant needed to fill the calyceal system. 13 out of 23 patients in the control group required more than one instillation. Both study group and control group had similar minor side effects like loin pain and fever. Complications reported were 15% and 13% for study and control group respectively.

Conclusion

Based on our study we suggest that single dose of povidone iodine0.2% with contrast agent instillation under fluoroscopic guidance is safe and efficacious. It gives comparable results to that of multiple instillation regimens previously done. Fluoroscopic guidance helps to optimally fill the pelvi-calyceal system. As we can directly see the filling, overfilling of the system and resultant complications such as pyelo-interstitial and pyelo-venous backflow could be avoided As single instillation was as effective as multiple instillation, the procedure can be done as a day care procedure without the need for prolonged ureteric catheterizations and hospitalization. The drawback of the study is shorter follow-up. However, our results suggest that use of fluoroscopy for instillation of povidone iodine with contrast agent is safe, inexpensive, effective, minimally invasive and is associated with shorter hospital stay. Also the procedure can be easily and safely reapplied in patients with recurrence.

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