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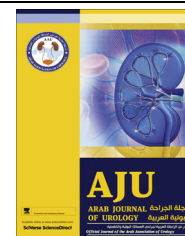
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ORIGINAL ARTICLE

Ethanolamine oleate vs. absolute ethanol as sclerosing agents for treating symptomatic simple renal cysts



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KEYWORDS

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ABBREVIATIONS

EO, ethanolamine
oleate;
AE, absolute ethanol;
US, ultrasonography

Abstract Objectives: To compare the efficacy and safety of ethanolamine oleate (EO) as a sclerosing agent, vs. absolute ethanol (AE), in the treatment of symptomatic simple renal cysts.

Patients and methods: Between November 2009 and October 2012, 46 patients were prospectively randomised into two groups. All patients presented with a simple renal cyst underwent ultrasonographic aspiration and injection of a sclerosing agent. In group 1, 25 patients had the cyst injected with EO, and in group 2, 21 were treated with AE. One injection was used in cysts of < 200 mL and two injections were used in larger cysts. Complete and partial success were defined as complete cyst ablation or a > 50% reduction in cyst volume with symptomatic relief, respectively. Patients were followed up using semi-annual ultrasonography and computed tomography for 2 years.

Results: Sclerotherapy was technically successful in all patients. There was no significant difference in cyst volume between the groups. After ≈2 years of follow-up there was complete symptomatic relief in both groups, and the overall radiological

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success rate was 100% of both groups, at 79% complete and 21% partial in group 1, and 83% complete and 17% partial in group 2. The frequency of transient complications in the form of microscopic haematuria was 7% and 13%, and of low-grade fever in 4% and 10% in groups 1 and 2, respectively.

Conclusion: EO can replace AE as a sclerosing agent for symptomatic simple renal cysts, as it has comparable efficacy with higher safety and tolerance.

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Introduction

Renal cysts are an acquired cystic disease of the kidney that mostly affects the elderly, with an incidence of $\approx 50\%$ in patients aged >50 years, as reported in autopsy studies [1,2]. Most renal cysts are asymptomatic lesions, incidentally discovered during radiological examinations, e.g., ultrasonography (US), CT, MRI and IVU for urological complaints or for other abdominal problems. Patients with symptomatic cysts present either with flank pain (in most cases), hypertension, haematuria, infection or pelvi-calyceal obstruction [3]. In some rare cases they can present as an abdominal mass [4].

Symptomatic simple renal cysts must be treated, whilst asymptomatic cysts only require a follow-up. Since 1970, percutaneous aspiration of renal cyst with or without injection of a sclerosing agent has become a minimally invasive, safe and low-cost method for managing symptomatic simple renal cysts [5]. Absorption of residual injected ethanol from the renal parenchyma leads to renal cell necrosis [6]. In the present study we used the sclerosing agent ethanolamine oleate (EO), which acts by inflammatory reaction on the endothelial lining of the cysts, leading to scarring and possible cyst ablation, with adhesive occlusion of the cyst, and compared the efficacy and safety of EO to that of absolute ethanol (AE), a commonly used sclerosing agent.

Patients and methods

After approval of ethics committee board at our institution, the present clinical trial started with informed written consent obtained from the patients. Between November 2009 and October 2012, 46 patients with symptomatic simple renal cysts were enrolled for percutaneous sclerotherapy (US-guided) with one of the agents after applying strict inclusion and exclusion criteria. For inclusion, the patient had a simple renal cyst on US that was of Bosniak classification class I, or ipsilateral flank pain due to a renal cyst (not colicky, not related to posture), a cyst volume of <500 mL. Patients were excluded if they had polycystic kidney disease, cystic dysplastic kidneys, previously treated cysts, or cysts suspected of harbouring malignancy. All patients were

evaluated by laboratory investigations, and renal cysts were diagnosed by US or CT.

Technique of cyst ablation

The procedure started with the administration of prophylactic antibiotics 1 h before the intervention. The patient was placed prone, and US guidance used to select the puncture site and correct tract, the site then being infiltrated with a local anaesthetic. The cyst was then punctured using an 18 G needle, and a J-tip guidewire then introduced into the cyst; the puncture needle was removed and a 6-F pigtail catheter inserted into the cyst over the guidewire. The first 20 mL of aspirated fluid was sent for cytological, chemical and bacteriological tests. If the cyst volume was <200 mL the cyst was completely evacuated, followed by injection with the sclerosing material, i.e., EO in group 1 and AE in group 2, according to the study protocol. The injected volume of sclerosant was 25% of the aspirated fluid volume. The pigtail catheter was then clamped for 30 min. We allowed free ambulation of the patient in different positions, to facilitate contact of the sclerosant with the cyst wall. The catheter was then opened, the sclerosant evacuated, the cyst contents being assessed by syringe aspiration, and finally the catheter was removed.

In cysts of >200 mL the same steps were as for small cysts until complete cyst drainage, when the pigtail catheter was retained for 3 h and the injection of sclerosant repeated, with closure of the pigtail and free ambulation of the patient for 30 min. The pigtail catheter was opened to allow complete drainage of the cyst content, and then removed. We used fluoroscopy during cyst aspiration of para-pelvic and para-ureteric cysts, by injecting 20 mL of ionic contrast medium into the cyst after aspirating 40 mL of cyst fluid, to delineate the cyst wall and thus exclude any communication of the cyst with the collecting system or the occurrence of extravasation during the procedure in nine patients.

Each patient was assessed for any complications such as fever, haematuria and pain. The patient was discharged home on the same day. Patients were followed up at 3 months and then every 6 months by assessing the previous complaint, and evaluation by US (or multi-slice CT in some patients). Full improvement in

the clinical symptoms and complete disappearance of the cyst were considered 'complete success', whilst relief of symptoms with a > 50% reduction in cyst volume was considered as a 'partial success'. The treatment was considered to have failed if > 50% of the original cyst volume recurred and/or there was persistence of the presenting clinical symptoms.

Statistical analysis comprised a *t*-test, chi-squared test and Fisher's exact test, as appropriate, to compare data before and after treatment in both groups, with *P* < 0.05 considered to indicate statistical significance.

Results

The study included 46 patients, 25 in group 1 (with 28 cysts) and 21 in group 2 (with 24 cysts). All procedures were performed with no technical difficulties or major complications. All patients were discharged on the same day of treatment, with no hospital admission. The pre-operative demographic characteristics (age, sex, laterality of the cyst, cyst volume, and clinical presentation) showed no statistically significant differences between the groups (Table 1).

Table 1 Patient demographics, cyst characteristics, clinical presentation, imaging method and number of injections, follow-up, radiological response and transient adverse effects.

Mean (SD) or <i>n</i> (%) variable	EO (28)	Ethanol (24)	<i>P</i>
Age (years)	53.7 (5.7)	51.8 (8.5)	0.41
<i>Sex</i>			
Male	15 (54)	13 (54)	0.96
Female	13 (46)	11 (46)	
<i>Laterality</i>			
Right	15 (54)	12 (50)	0.51
Left	13 (46)	12 (50)	
Cyst volume	228.8 (123.3)	213.5 (106)	0.80
<i>Clinical presentation</i>			
Pain	15 (54)	14 (58)	0.98
Haemorrhage	7 (25)	5 (21)	
Mass	4 (14)	3 (13)	
<i>Imaging</i>			
US	23 (82)	20 (83)	
US + fluoroscopy	5 (18)	4 (17)	
<i>Number of injections</i>			
One	20 (71)	19 (79)	0.38
Two	8 (29)	5 (21)	
Follow-up (months)	26.2 (10.3)	25.3 (9.7)	0.59
Range	(6–42)	(6–42)	
<i>Radiological response</i>			
Complete	23 (82)	20 (83)	0.47
Partial	5 (18)	4 (17)	
<i>Adverse effects</i>			
Fever	1 (4)	2 (10)	0.024
Haemorrhage	2 (7)	4 (13)	
Total	3 (11)	6 (22)	

Procedures were carried out under US guidance in all cysts (52) and were completed under fluoroscopy in nine (17%) of the cysts (Table 1). Chemical analyses of the aspirated fluid showed similar values to those in serum for creatinine and electrolytes, and no malignant cells were detected on cytological examination. The number of injections in both groups was determined by cyst volume, with cysts of < 200 mL injected once and > 200 mL injected twice. Overall, 39 cysts received one injection and 13 required two (Table 1).

After a mean (SD, range) follow-up of 26.2 (10.3, 6–42) months in group 1 and 25.3 (9.7, 6–42) months in group 2, the overall radiological success rate was 100% in both groups, with 79% complete and 21% partial in group 1, and 83% complete and 17% partial in group 2. Complete symptomatic relief was obtained in all patients, with no statistically significant difference between the groups. There was a statistically significant difference between the groups in the frequency of transient complications, in the form of microscopic haematuria, of 7% and 13%, and low-grade fever, in 4% and 10% of groups 1 and 2, respectively (Table 1).

Discussion

To date there are no firm data on the optimum sclerosant for renal cyst ablation, and there is debate about using one injection or several injections. Despite the widespread use of AE as a common sclerosant for renal cyst ablation, the available data on its efficacy and adverse effects remains insufficient [7,8].

Many studies report the superiority of multiple sessions of AE sclerotherapy over a single session [3,9]. However, there are many studies using the single-session protocol despite it being inferior for the complete regression of renal cysts vs. multiple-session sclerotherapy [7,10]. Given the previous controversies about the adverse effect of unevacuated AE after injection, and its absorption by the renal parenchyma resulting in renal cell necrosis, in the present study we used another sclerosant and compared the results with AE.

Renal cysts clinically present with variable degrees of pain [11] and/or haematuria [9,10], mass [11,12], and hypertension [11,13]. In the present study, patients presenting with pain, haematuria, mass and hypertension comprised 54%, 25%, 14% and 7% in group 1, and 58%, 21%, 13% and 8% in group 2. Renal cysts affect both kidneys, with no lateral predominance, as shown in the present study, where the right/left incidence was 15/13 in group 1 and 12/12 in group 2, similar to that reported by Ham et al. [6], of 23/27 in group 1 and 29/32 in group 2, and by Mohsen and Gomha [12] (26/34, right to left, respectively).

The treatment in both groups provided clinical relief of symptoms and excellent radiological success rates in the form of complete cyst ablation in 82% and 83% in

groups 1 and 2, respectively, and a reduction in cyst volume by > 50% of the original cyst in 18% and 17%, as partial success. These results are comparable with those of Ham et al. [6], who compared multiple sessions using one injection with 95% ethanol, with OK-432 (a new sclerosant used previously for treating cystic-hygroma and cystic lymphangioma, with no clinical toxicity), and the study of Mohsen and Gomha [12] which showed complete cyst ablation in > 90% of cysts of < 500 mL, and another study by Porpiglia et al. [13], who reported 98% cyst ablation after cyst aspiration and three successive injections with alcohol at 24-h intervals.

In the present study the procedure was conducted as an outpatient method, with no need for hospital admission, as reported by Li et al. [14], who used one injection with AE in one session, and one injection with bleomycin in one session, respectively, in cysts of < 200 mL. Also, Li et al. [15] used several injections in one session for cysts of > 200 mL, as in the present study. However, unlike in the study of Fontana et al. [16] and Phelan et al. [17], who maintained the percutaneous tube for 2, and 3–5 days, respectively, other studies [6] retained the tube for 24 h in the alcohol-treated group, and Mohsen and Gomha [12] did so in patients with a cyst volume of > 500 mL.

The percutaneous management of renal cysts is usually completed with no significant complications, as in the present and many previous studies, with no reported major complications [12,18], although there is one report of a case complicated by severe bleeding in the cyst during percutaneous aspiration [16].

In the present study transient adverse effects occurred during the procedure, e.g., low-grade fever in 4% and 10% in groups 1 and 2, respectively, with microscopic haematuria in 7% and 13%, respectively, with an apparent evident reduction in adverse effects in the EO group. Alcohol is the most common sclerosant used for symptomatic renal cyst ablation, either AE or 95% ethanol. However, the concerns about renal parenchymatous intoxication from alcohol injections, and the infrequent use of other sclerosants with variable degrees of success not yet determined, like povidone-iodine, OK-432, bismuth phosphate, minocycline hydrochloride, bleomycin, hypertonic saline, and β -emitting radionuclide, induced us to conduct the present study [6].

In the present study the results for efficacy were excellent in both groups, with no technical problems or major complications during the procedure, despite a significant reduction in adverse effects of the ablation procedure in the EO group. EO has been used previously for sclerosing oesophageal varices as a standard treatment, but is rarely used for symptomatic renal cyst ablation, as done by Yamamoto et al. [19], who reported excellent results but with only a few patients. We used EO in a significant number of cysts, but there is a need for wider multi-centre studies to consolidate these results, as EO is an easily

available, low-price sclerosant with no concerns for cell necrosis in the renal parenchyma, as some have reported for AE.

In conclusion, the combination of percutaneous drainage (US-guided) and injection with a sclerosant, is effective for treating simple renal cysts. EO has a comparable sclerosing efficacy to AE, but with a better complication profile. The present preliminary results after using EO suggests that the results should be consolidated in multi-centre studies with EO, a material that is better tolerated and with minimal adverse effects.

Conflict of interest

None.

Source of funding

None.

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