

# EFFICACY AND SAFETY OF LUBRICATING JELLY INSTILLATION TO PREVENT RETROPULSION DURING URETEROLITHOTRIPSY FOR URETERAL STONES

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## ABSTRACT

**Objective:** We studied the efficacy and safety of lubricating jelly instillation before ureterolithotripsy for prevention of retropulsion and improvement in stone-free rate. **Material & methods:** We enrolled 22 subjects with ureteral stone in this prospective, randomized, single-blind and controlled clinical trial. Each subject was randomly assigned to the lubricating jelly instillation group (n=11) and control group (n=11). Ureteroscopy and lithotripsy was performed according the standard protocol, using 9.8 F semirigid ureteroscope and pneumatic lithotripter. A 6 F ureteral catheter was advanced beyond the stone, and lubricating jelly was instilled through the catheter lumen. Retropulsion and the presence of residual fragments were evaluated with plain kidneys, ureters and bladder x-ray and ultrasonography, or Non Contrast-enhanced Computed Tomography. Any complication was reported and graded using the Modified Clavien Classification System. **Results:** The 2 groups had comparable preoperative characteristics. There were no statistically significant difference between the lubricating jelly instillation group and control group regarding the retropulsion rate (54.5% vs 72.7%,  $p=0.375$ ), the stone-free rate (54.5% vs 36.4%,  $p=0.392$ ), and the complication rate (45.5% vs 54.5%,  $p=0.670$ ). **Conclusion:** Lubricating jelly instillation during ureterolithotripsy has limited value for prevention of retropulsion and improvement in stone-free rate.

**Keywords:** Ureterolithotripsy, retropulsion, lubricating jelly instillation.

## ABSTRAK

**Tujuan:** Kami mempelajari efikasi dan keamanan instilasi jeli pelumas sebelum dilakukan ureterolitotripsi untuk menurunkan angka retropulsi dan meningkatkan angka bebas batu. **Bahan & cara:** Penelitian ini adalah sebuah uji klinis acak terkontrol dengan desain prospektif. 22 pasien dibagi secara acak ke dalam kelompok instilasi jeli pelumas (n=11) dan kelompok kontrol (n=11). Ureteroskopi dan litotripsi dilakukan menurut protokol standar, menggunakan ureteroskop semirigid 9.8 F dan litotriptor pneumatik. Kateter ureter 6 F kemudian dimasukkan hingga melewati batu, dan jeli pelumas diinstilasikan melalui lumen kateter. Retropulsi dan adanya fragmen residual dievaluasi dengan foto polos abdomen dan ultrasonografi, atau non contrast enhanced computed tomography. Semua komplikasi dilaporkan dan diklasifikasikan menurut Modified Clavien Classification System. **Hasil:** Tidak didapatkan perbedaan yang bermakna secara statistik antara kelompok instilasi jeli pelumas dan kelompok kontrol dalam hal angka retropulsi (54.5% vs 72.7%,  $p=0.375$ ), angka bebas batu (54.5% vs 36.4%,  $p=0.392$ ), dan angka komplikasi (45.5% vs 54.5%,  $p=0.670$ ). **Simpulan:** Instilasi jeli pelumas tidak bermanfaat untuk mencegah retropulsi dan meningkatkan angka bebas batu pada ureterolitotripsi.

**Kata kunci:** Ureterolitotripsi, retropulsi, instilasi jeli pelumas.

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## INTRODUCTION

Urinary stone disease is one of the most common afflictions of the urinary tract, with life-time prevalence is estimated at 1–15%.<sup>1</sup> With westernization of global culture, the site of stone

formation has migrated from the lower to the upper urinary tract.<sup>1</sup> Most of the ureteral stones originate from the renal calyces, which migrate to the pelvis and subsequently to the ureter.<sup>2</sup>

Shock wave lithotripsy (SWL) and ureteroscopy with lithotripsy (ureterolithotripsy/URSL)

remain the 2 primary treatment modalities for the management of symptomatic ureteral calculi.<sup>3</sup> However, one study showed that URSL is the most cost-effective treatment strategy for ureteral stones at all locations after observation fails.<sup>4</sup> The safety of this procedure is well-established, with overall and major complication rates of 10–20% and 0–6%, respectively.<sup>5</sup>

Despite the undoubted value of this procedure, some fundamental obstacles remain to limit its success. One of them is retrograde displacement of a calculus within the ureter when any form of kinetic energy is applied in an attempt to fragment it. This retropulsion movement has been reported in 3–15% of distal ureteral stones and 28–48% of proximal ureteral stones.<sup>6</sup> Stone retropulsion may result in decreased stone-free rates, increased operative time and the need for subsequent procedures, as well as increased patient morbidity and health care costs.<sup>6</sup>

A number of mechanical devices have been introduced to address the problem of retropulsion, with each of them have their own strength and limitation. The ideal device would be inexpensive, easy to deploy, prevent fragment migration effectively and allow the passage of intracorporeal lithotriptors, guidewires and stents following stone fragmentation. At this moment, the ideal anti-retropulsion method is still to be determined.<sup>7</sup> One of the major problem is additional cost required for anti-retropulsion devices. Ursiny and Eisner reported that the use of anti-retropulsion device with average cost US \$278 will be cost-effective if the retropulsion rate in a given urologic center exceeds 6.3%.<sup>8</sup> However, this additional cost is still become a considerable problem in several socio-economic settings, especially in the developing countries.

In 2004, Ali and colleagues suggested a new method to prevent retropulsion during URSL, using lubricating jelly instilled proximal to the stone before applying the kinetic energy.<sup>9</sup> This technique requires no additional cost. The success that they reported has led several other researchers to evaluate the efficacy of this technique in a randomized clinical trial (RCT), which also resulted in favorable outcomes.<sup>10,11</sup> However, some of the technical aspects of this technique remain questionable. Previous authors used 2 mL of lubricating jelly to prevent retropulsion, regardless of the degree of hydronephrosis and hydroureter. Furthermore, the safety of this procedure has not been reported using standardized method. The Modified Clavien

Classification System (MCCS) is one of the standardized systems used for reporting and classification of surgical complications that is recommended by the European Association of Urology (EAU) guidelines panel.<sup>12</sup> In 2012, Mandal and colleagues reported the first study that prospectively evaluate the complications of URSL using the MCCS. They reported it to be easy, straight forward and not time consuming method.<sup>13</sup>

This study was designed to re-evaluate the efficacy and safety of lubricating jelly instillation for preventing retropulsion during URSL, using calculated volume of the jelly, depending on the degree of hydroureter. Furthermore, the safety of this technique was evaluated using MCCS as standard reporting system recommended by the EAU guidelines panel.

## OBJECTIVE

We studied the efficacy and safety of lubricating jelly instillation before ureterolithotripsy for prevention of retropulsion and improvement in stone-free rate.

## MATERIAL & METHODS

After institutional review board approval and informed consent, 22 patients with ureteral stones requiring ureterolithotripsy were enrolled in this prospective, randomized, controlled trial. Patients were randomized into 2 groups (11 patients in lubricating jelly instillation/treatment group, 11 patients in control group) in an alternate manner.

The inclusion criteria were patients with ureteral stone 2 cm or less, either radioopaque or radioluscent. The ipsilateral ureter should be visualized either using Intravenous Urography (IVU) or Non Contrast-enhanced Computed Tomography (NCCT) of the abdomen, so that the dimension of the ureter can be estimated using mathematical calculation. The exclusion criteria were multiple ipsilateral ureteral stones, concomitant kidney stones, stones located 2 cm or less from the ureteropelvic junction (UPJ), stone impaction, ureteral stenosis documented from preoperative or intraoperative evaluation, jelly requirement more than 40 mL, retropulsion that occurred before lithotripsy had been performed and in case of stone removal using forceps or basket. All operations were performed by residents in the 5<sup>th</sup> year of training.

All patients underwent URSL under regional or general anesthesia, based on the anesthesiologist discretion, using 9.8Fr semirigid ureteroscope (Storz, Germany). After reaching the stone, in the treatment group, a 6Fr ureteral catheter with a cut tip was advanced beyond the stone. The lubricating jelly was then instilled in the ureteral lumen through the ureteral catheter. The volume of the jelly instilled was based on the estimation of ureteral volume, according to the ureteral width and stone-UPJ distance, which was readily seen from the IVU or NCCT. The jelly used in this study was M-Y jelly (Jayamas Medica Industri, Sidoarjo, Indonesia) with viscosity 6000 mPas. The jelly was diluted with normal saline solution in ratio 1 : 1, to overcome the difficulty from instilling the very viscous jelly through the small ureteral catheter lumen.

Lithotripsy was then performed in the same manner for both groups, using the Lithosplit (Apex Meditech, Pune, India) with 4500 kPa pressure and a 5Fr rod. Retropulsion was determined intraoperatively, and defined as retrograde movement of stone or stone fragments more than 2 cm from its original location, as seen from intraoperative fluoroscopy. After completion of the procedure, the remaining amount of jelly was washed out with saline irrigation, and DJ stent was then inserted in all patients. The operative time was calculated from the time of cystoscope insertion to completion of urethral catheter insertion.

All patients were evaluated using Kidneys, Ureters and Bladder (KUB) x-ray 1 day after operation. Ultrasonography (USG) was performed in cases of radioluscent stone, or unclear visua-

lization of the residual fragments due to excessive bowel gas or fecal material. All patients with visible residual fragments on KUB and/or USG with size 4 mm or more will be considered non-stone free. Conversely, those without visible residual fragments on KUB or USG were then underwent DJ stent removal 2 weeks postoperatively, then re-evaluated using KUB for radioopaque stone, or NCCT for radioluscent stone, to accurately determined the presence of residual fragments. Complications were documented from the time of cystoscope insertion until 2 weeks postoperatively, and graded using the MCCS.

The independent t-test was used to compare operative time in the 2 groups. Crosstab analysis was used to compare the retropulsion, stone-free and complication rates in the 2 groups. The independent t-test was also used to compare the mean age, stone length and width, stone surface area, ureteral width, stone-UPJ distance and ureteral volume. In all tests,  $p < 0.05$  was taken to indicate significance.

**RESULTS**

Overall, 22 patients entered the study (11 received jelly instillation and 11 controls). The 2 groups were comparable with regard to preoperative characteristics (table 1).

Although the mean operative time was slightly longer in the treatment group (49.6 vs 47.7 minutes), the difference was not significant ( $p=0.704$ ). Retropulsion occurred in 6 patients (54.5%) in the treatment and 8 patients (72.7%) in the control group. This difference was not

**Table 1.** Comparison of preoperative characteristics between the 2 study groups.

Parameters	Treatment Groups		p
	Lubricating jelly instillation (n=11)	Control (n=11)	
Age	47 years	50 years	0.573
Stone length	10.4 mm	10.7 mm	0.405
Stone width	5.9 mm	6.7 mm	0.344
Stone surface area	48.8 mm <sup>2</sup>	57.3 mm <sup>2</sup>	0.330
Ureteral width	6.9 mm	8.2 mm	0.091
Stone-UPJ distance	139.1 mm	135.7 mm	0.817
Ureteral volume	5.2 MI	6.3 mL	0.532

**Table 2.** Comparison of the study results between the 2 study groups.

Parameters	Treatment Groups		p
	Lubricating jelly instillation(n=11)	Control (n=11)	
Operative time	49.6 minutes	47.7 minutes	0.704
Retropulsion rate	6 (54.5%)	8 (72.7%)	0.375
Stone-free rate	6 (54.5%)	4 (36.4%)	0.392
Complication rate	5 (45.5%)	6 (54.5%)	0.670
MCCS grade I	4 (36.4%)	6 (54.5%)	0.392
MCCS grade II	1 (9.1%)	0 (0%)	0.306

statistically significant ( $p=0.375$ ). At the end of the study, 6 patients (54.5%) in the treatment and 4 patients (36.4%) in the control group were stone-free. This difference was also not statistically significant ( $p=0.392$ ). The complication rate between the 2 groups was also not statistically significant (table 2). There were no major complication (MCCS grade III or more) occurred in both groups.

## DISCUSSION

URSL is currently the treatment of choice for management of ureteral stones, with reported stone-free rate for proximal, mid and distal ureteral stones were 81%, 86% and 94% respectively (Preminger). Lower stone-free rate is usually due to difficulty of access and retropulsion. The overall stone-free rate in this study is relatively low (45.5%), and retropulsion is the only contributing factor of these unfavorable result.

Several devices have been invented to prevent retropulsion, including balloon, stone cone and baskets, but these add to the costs. This financial reason limits the use of anti-retropulsion devices in this center, despite a relatively high retropulsion rate.

Ali and colleagues proposed a new method to prevent retropulsion using instillation of lubricating jelly proximal to the stone before stone fragmentation with pneumatic lithotripter.<sup>9</sup> Efficacy of this method has been established by 2 subsequent RCTs.<sup>10,11</sup> This method requires no additional cost, so it might be ideal to be applied in this center. However, several theoretical issues make the value of this technique remain questionable. All of the previous studies instilled 2 mL of jelly, regardless of the degree of hydronephrosis and hydroureter

suffered by the patients. Theoretically, to create an effective mechanical barrier, sufficient amount of jelly is required to adequately fill the ureteral lumen. Therefore, different amount of jelly would be needed for different degree of hydroureter. In this study, the volume of the jelly instilled was calculated using the estimation of ureteral volume, based on the imaging studies (IVU or NCCT). Even after using this theoretically better method, this study failed to show the benefit of lubricating jelly instillation to prevent retropulsion and improving stone-free rate. Therefore, this study serves as an opposing view regarding the efficacy of lubricating jelly instillation to prevent retropulsion. In addition, when compared to the other anti-retropulsion device (the Dretler stone cone), low efficacy of this technique has been reported.<sup>14</sup>

Another theoretical challenge regarding the efficacy of this technique is the viscosity of the jelly itself. Study conducted by Ali and colleagues used instillation of KY jelly, whereas 2 subsequent RCTs used mixture of lubricating jelly with lidocaine 2%. Addition of lidocaine will reduce the viscosity of the jelly, thus reducing its efficacy, as reported in the previous RCTs.<sup>10,11</sup> Using undiluted lubricating jelly, Ali and colleagues reported 100% success rate. However, they also reported difficulty in injecting a very viscous jelly through the lumen of small ureteral catheter.<sup>9</sup> In this study, the jelly used was MY jelly with viscosity of 6000 mPas, and diluted with normal saline solution in 1:1 ratio. The final viscosity was unknown, and it becomes a technical limitation of this study. None of the previous similar studies had reported the viscosity value of the jelly used in their studies.<sup>9,10,11</sup>

The surprisingly high retropulsion rate and low stone-free rate suggested by this study might be

associated with the operator experience. Schuster and colleagues reported that surgeon's experience is an independent predictor of unfavorable results during and after URSL.<sup>5</sup> Further evidence was also provided by other authors.<sup>13,15</sup> Further study is required to evaluate and compare the result of URSL performed by residents and consultants in this center.

This study has several limitations. As were the previous studies, this study evaluate the efficacy of lubricating jelly instillation only based on the occurrence of retropulsion. The function of the jelly as mechanical barrier is still poorly documented. Another limitation is the inability to measure the retropulsion distance accurately. This study defined retropulsion as retrograde displacement of stone fragments 2 cm or more from its original location. The distance was measured made with assumption that the ureter follows a straight course. This method was not 100% accurate, since the dilated ureter due to obstruction is sometimes tortuous.

## CONCLUSION

This study suggested that lubricating jelly instillation showed no benefit in preventing retropulsion and improving stone-free rate during URSL with pneumatic lithotripter. Nevertheless, this technique was not associated with increased complication rate of URSL. Another method is required to address the ret ropulsion problem, especially in center with high retropulsion rate.

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