

Dimethylpolysiloxane in the Preparation of Adult Excretory Urography

Olivia Kuswanto, dr; Prof. Nurlela Budjang, dr; Marnansjah D. Rachman, dr; Subur Budiman Setjaatmadja, dr; Azwar Boer, dr

Abstrak

Telah dilakukan penelitian prospektif mengenai peran dimethylpolysiloxane dalam persiapan urografi intravena terhadap kualitas diagnostik foto yang dihasilkan. Penelitian dilakukan terhadap 161 pasien rawat jalan (72 wanita, 89 pria) yang menjalani pemeriksaan urografi intravena di Bagian Radiologi FKUI-RSCM pada bulan Agustus 1991 s/d Oktober 1991. Rentang usia pasien-pasien tersebut antara 15-65 tahun. Secara acak, pasien-pasien dikelompokkan dalam 2 kelompok : kelompok dimethylpolysiloxane (87 pasien) menerima dimethyl-polysiloxane, dan kelompok plasebo (74 pasien) menerima gula pasir. Lama puasa berkisar antara 7,5-13,7 jam. Kepada setiap pasien diberikan lembar persiapan pemeriksaan urografi intravena. Bahan kontras yang dipergunakan adalah Urografin 76 % sebanyak 20 ml. Dari kedua kelompok tersebut, tidak dijumpai adanya efek samping selama persiapan maupun saat pemeriksaan urografi intravena. Foto-foto yang dinilai adalah foto polos abdomen, foto urografi 5 menit dan 20 menit pasca kontras. Foto-foto tersebut dinilai secara terpisah oleh 3 orang ahli Radiologi. Hasil penilaian dinyatakan dalam skala 1-5, sesuai dengan kriteria kurang sekali, kurang, sedang, baik dan sangat baik. Data-data penilaian kemudian di analisis dengan metoda statistik Mann-Whitney U-Wilcoxon Rank Sum W Test. Dari hasil penelitian ini tampaknya pemberian dimethylpolysiloxane dalam persiapan urografi intravena memberi perbedaan bermakna secara statistik dalam kualitas foto urografi dibandingkan plasebo ($P < .05$, two tail).

Abstract

A prospective randomized study was undertaken to determine whether dimethylpolysiloxane as bowel preparation improves the diagnostic quality of excretory urogram. From August 1991 to October 1991, we analyzed 161 outpatients (72 female, 89 male) who underwent excretory urography on an elective basis at the Radiology Department of Dr. Cipto Mangunkusumo Hospital, Jakarta. The age ranged from 15 to 65 years. They were randomized into 2 groups: dimethylpolysiloxane group (87 patients) received dimethylpolysiloxane, and placebo group (74 patients) received sugar before urography. The duration of fasting time ranged from 7,5 to 13,7 hours. The contrast material was Urografin 76 % (20ml). There were no side effects reported from both groups. The evaluation of examination including Kidney, Ureter, Bladder (KUB) radiograph, a 5-minutes compression radiograph, and 20 minutes radiograph after releasing the compression was interpreted individually by 3 radiologist. The outcome was graded as very poor, poor, moderate, good, and excellent on a scale of 1 to 5. Using Mann-Whitney U-Wilcoxon Rank Sum W Test, it revealed that the administration of dimethylpolysiloxane as bowel preparation compared to that of placebo made statistically significant difference to the diagnostic quality of urogram ($P < .05$, two tail).

Keywords : Dimethylpolysiloxane, Excretory urography

INTRODUCTION

In spite of the advent of the new imaging modalities, the excretory (intravenous) urography remains an important technique for the visualization of the pyelocalyceal system, ureter, and bladder. By urography, morphological studies will be less invasive and led to very important physiological trends.^{1,2,3} The success of the examination depends upon several fac-

tors : (1) both the referring clinician and the radiologist should carefully consider whether or not some imaging techniques will provide the information more accurately, more safely, and/or at a lower cost;^{4,5,6} (2) the patient's bowel should be well prepared, since residual bowel gas and feces may obscure or mimic renal masses;^{5,6} (3) the radiology equipment, films, screens, and exposure techniques must be the finest available for this type of examination.^{4,6}

The administration of bowel preparation before an excretory urography is a time-honored procedure and one that remains prevalent in many radiological departments. Although there has been disagreement for several years regarding the need prior bowel preparation, it is still recommended to use some form of catharsis before urography. It is difficult to evaluate the X-ray pictures in many cases of urography, owing to the fact that the urinary tract can be blurred by the presence of air shadows, and the use of laxatives does not appear to be the complete answer.⁶ Bowel preparation is probably unnecessary as tomography can be employed when overlying gas and fecal shadows are a problem.⁷ But in Indonesia, where tomography is not available in every rural areas, bowel preparation is still important before urography (without tomography).

In this paper we present the quality of adult intravenous or excretory urogram with use of dimethylpolysiloxane compared to placebo (sugar) during the preparation procedures.

MATERIALS AND METHODS

The study was done at the Radiology Department Dr. Cipto Mangunkusumo Hospital, Jakarta between August 1991 and October 1991. It was performed to the adult outpatients (age above 15 years old) referred for elective excretory urography to our department. Criteria for inclusion of subjects to the study were: (1) adult outpatients referred for elective excretory urography (age above 15 years old); (2) patients should be in good general condition; (3) come to our department for the first time for excretory urography; (4) no allergic history to contrast media and or antacids; (5) no concomitant digestive problems; (6) normal renal function (blood urea and creatinine); (7) patients accepted for participating in this study.

Receptionist at patient registration selected patients who fulfilled the inclusive criterias. Patients were randomly assigned into two groups based on a list prepared by a computer. This study was double blind; the patients were not informed whether they received dimethylpolysiloxane or placebo, and the radiologists were not informed too whether they interpreted the dimethylpolysiloxane urogram or placebo. Patient received the instruction list, a plastic bag containing dimethylpolysiloxane coded as P1 or P2 for placebo, and was asked to bring back the plastic at the day of the examination.

The instruction list consisted of procedures during the preparation day: (1) low residue diet (porridge and ketchup) within two days preparation; (2) taking one capsule either P1 or P2 three times daily

after each meal; (3) fasting since 7.00 pm on the preceeding day of the examination; (4) taking 30 grams magnesium sulfate with a glass of water at 8.00 pm; (5) withholding of fluids since 10.00 pm; (6) smoking was not allowed; (7) coming to the Radiology Department at 8.00 am at the day of the examination. The preparation time would be within two days and the examination performed on the third day.

Each dimethylpolysiloxane capsule consisted of 40 mg dimethylpolysiloxane, and placebo capsules of 40 mg sugar. These two kinds of capsules were supplied in identical color and size. Every 6 capsules was packed in a plastic bag.

The examination was performed by a senior radiographer. Questioners designed for the study were filled in by the first author as a principal investigator before each examination. The questioner consisted of personal data of patient (age, sex, level of education, body weight), and the preparation (did they take low residue diet, did they take all the capsules and cathartic, duration of fasting, did they smoke). Any side effect caused by taking the capsules was also recorded.

After making the interview, the radiographer performed the examination in standard way. The contrast material Urografin 76 % (20 ml) was injected in an antecubital vein within a period of 2- 3 minutes. The body thickness was measured and the compression was applied on both ureter area. All exposure were made at the end of the same phase of breathing - at the end of exhalation. The examination for this study consisted of: (1) a kidney, ureter, and bladder (KUB) radiograph; (2) a 5-minute compression radiograph of the renal area; (3) and radiograph including the whole urinary tract after release of compression at 20 minutes.

Evaluation of the film quality was performed separately, firstly for distribution of gas and feces, and secondly the clarity of each part of the urinary tract and its surrounding organs. The films were interpreted by three radiologists that unaware of which films were on placebo patients and which were on dimethylpolysiloxane treated patients.

The distribution of gas and feces was graded as (scale 1 to 5):

- Very poor (scale 1): too much gas and feces shadows in the urinary tract area, and each part of the urinary tract could not be evaluated.
- Poor (scale 2): much gas and feces shadows in the urinary tract area that blurred the urinary tract details.
- Moderate (scale 3): moderate gas and feces shadows in the urinary tract area,

but the organ details were still clear.

- Good (scale 4) : less gas and feces shadows, and the urinary tract details were clear.
- Excellent (scale 5) : no gas and feces shadows in the urinary tract area.

The clarity of each part of the urinary tract and its surrounding organs was graded as (scale 1 to 5) :

- Very poor (scale 1) : could not be evaluated.
- Poor (scale 2) : difficult to be evaluated.
- Moderate (scale 3) : could be evaluated but not clear.
- Good (scale 4) : could be evaluated clearly.
- Excellent (scale 5) : could be evaluated very clearly.

The statistical analysis in differentiating placebo and dimethylpolysiloxane result was done by means of Mann-Whitney U- Wilcoxon Rank Sum W Test. The analysis based on mean ranks of interpretation of gas and feces shadows in abdominal area and the clarity of each part of urinary tract according to three radiologists on KUB film, 5-minutes urogram, and 20-minutes urogram. Scale 1 and 2 were graded as poor, scale 3 and 4 as good, and scale 5 as excellent. The interpretation of preparation quality or the distribution of gas and feces shadows was graded in the same way. A P value of mean rank less than .05 (two tail) was considered statistically significant. We considered that there was a significant difference if at least two radiologists were in agreement in each result.

RESULTS

During August 1991 to October 1991 there were 178 outpatients (dimethylpolysiloxane group 91 patients, placebo group 87 patients) fulfilled the inclusive criteria and participated in the study. We excluded 17 patients from this analysis for the following reasons : 8 patients showed no representative films such as asymmetrical body position, the three films (KUB, 5 minutes, and 20 minutes urography) were not available completely, and the exposure techniques were not optimal; 2 patients forgot to take all the capsules within the preparation day; 3 patients refused to take magnesium sulfate completely because of the bitter taste; 2 patients did not come on the day of the examination; 1 patient did not take low residue diet, and 1 patient smoked within the preparation day.

Therefore, we analyzed 161 patients which consisted of 87 patients in dimethylpolysiloxane group,

and 74 patients in placebo group. Dimethylpolysiloxane group consisted of more male (60.9 %) and placebo group of more female (51.4 %). Most of the patients ranged in age from 30-44 years old (dimethylpolysiloxane group 40.2 %, placebo group 48.6 %), and in weight from 50 to 59 kgs (dimethylpolysiloxane group 31.4 %, placebo group 36.5 %). Most of them had already graduated from Senior High School (44.8 % in dimethylpolysiloxane group, 50 % in placebo group). The duration of fasting time ranged from 7.5-13.7 hours; 77.1 % of patients in dimethylpolysiloxane group, and 74.3 % patients in placebo group fasted more than 10 hours. In term of age, sex, body weight, level of education, and duration of fasting, statistically there were no significant differences between dimethylpolysiloxane and placebo group (Table 1). No side effects were recorded with either of the preparation.

Table 1. Some Characteristics of Patients and Related Factors

Characteristics	Placebo (N=74) n (%)	Dimethylpolysiloxane (N=87) n (%)	P value
Sex			0.1610
Male	36 (38.6)	53 (60.9)	
Female	38 (51.4)	34 (39.1)	
Age			0.45968
15-29 years	16 (21.6)	17 (19.5)	
30-44 years	36 (48.6)	35 (40.2)	
45-59 years	15 (20.2)	27 (31.2)	
≥ 60 years	7 (9.5)	8 (8.1)	
Weight			0.05770
30-39 kg	8 (11.0)	3 (3.5)	
40-49 kg	18 (24.7)	21 (24.4)	
50-59 kg	26 (36.5)	28 (31.4)	
60-69 kg	9 (11.0)	26 (30.2)	
≥ 70 kg	13 (17.8)	9 (10.5)	
Level of education			0.97622
Illiterate	2 (2.7)	3 (3.4)	
Elementary School	11 (14.9)	14 (16.1)	
Junior High School	12 (16.2)	16 (18.4)	
Senior High School	37 (50.0)	39 (44.8)	
Academy/University	12 (16.2)	15 (17.2)	
Duration of fasting			0.80495
< 10 hours	19 (25.7)	20 (22.9)	
≥ 10 hours	55 (74.3)	67 (77.1)	

The comparison according to poor (scale 1 and 2), good (scale 3 and 4), and excellent (scale 5) criteria :

KUB film

Poor quality was seen in 1-4 patients (1.2 % - 4.5 %) of dimethylpolysiloxane group, and in 2-6 patients (2.7 % - 8.1 %) of placebo; good quality was seen in 53-67

patients (60.9 % - 77.0 %) of dimethylpolysiloxane group, and in 60-70 patients (81.1 % - 94.6 %) of placebo; excellent quality was seen in 19-30 patients (21.8 % - 34.6 %) of di-methylpolysiloxane group, and in 2-11 patients (2.7 % - 14.8 %) of placebo.

All the results showed P value less than .05 except the interpretation of KUB by the first radiologist.

5 minutes urogram

Poor quality was seen in 8-11 patients (9.2 % - 12.6 %) of dimethylpolysiloxane group, and in 10-19 patients (13.5 % - 25.7 %) of placebo group; good quality was seen in 39-45 patients (44.8 % - 51.7 %) of placebo group; excellent quality was seen in 34-39 patients (39.1 % - 44.8 %) of dimethylpolysiloxane group, and in 10-15 patients (13.6 % - 20.3 %) of placebo group.

All the result of 5 minutes urogram showed statistically significant differences between dimethylpolysiloxane and placebo group ($P < .05$).

20 minutes urogram

Poor quality was seen in 1-4 patients (1.1 % - 4.6 %) of dimethylpolysiloxane group, and in 2-6 patients (2.7 % - 8.2 %) of placebo group; good quality was seen in 53-67 patients (60.9 % - 77.0 %) of dimethylpolysiloxane, and in 60-70 patients (81.1 % - 94.6 %) of placebo group; excellent quality was seen in 19-30

patients (21.8 % - 34.5 %) of dimethylpolysiloxane group, and in 2-11 patients (2.7 % - 14.8 %) of placebo group.

All the results of 20 minutes urogram showed statistically significant differences between dimethylpolysiloxane and placebo group ($P < .05$).

Preparation quality

Poor quality was seen in 8-11 patients (9.2 % - 12.6 %) of dimethylpolysiloxane group, and in 10-19 patients (13.5 % - 25.7 %) of placebo group; good quality was seen in 39-45 patients (44.8 % - 51.7 %) of dimethylpolysiloxane group, and in 42-54 patients (56.7 % - 72.9 %) of placebo group; excellent quality was seen in 34-39 patients (39.1 % - 44.8 %) of dimethylpolysiloxane group, and in 10-15 patients (13.6 % - 20.3 %) of placebo group.

The preparation quality showed statistically significant differences between dimethylpolysiloxane and placebo group ($P < .05$).

Interobserver variations in the grading of diagnostic quality were observed in Table 2.

The overall result showed significant difference between dimethylpolysiloxane and placebo group because at least two radiologists were in the same agreement.

Table 2. Comparison of Quality between Dimethylpolysiloxane and Placebo

Result	Radiologist I		Radiologist II		Radiologist III	
	Placebo n (%)	Dimethylpolysiloxane n (%)	Placebo n (%)	Dimethylpolysiloxane n (%)	Placebo n (%)	Dimethylpolysiloxane n (%)
Kidney-Ureter-Bladder						
Poor	3 (4.1)	1 (1.2)	2 (2.7)	1 (1.2)	6 (8.1)	4 (4.5)
Good	60 (81.1)	63 (72.4)	70 (94.6)	67 (77.0)	60 (81.1)	53 (60.9)
Excellent	11 (14.8)	23 (26.4)	2 (2.7)	19 (21.8)	8 (10.8)	30 (34.6)
P value	0.2414		0.0003		0.0007	
5-Minutes Urogram						
Poor	19 (25.7)	11 (12.6)	10 (13.5)	8 (9.2)	10 (13.5)	9 (10.4)
Good	42 (56.8)	40 (46.0)	54 (72.9)	45 (51.7)	49 (66.2)	39 (44.8)
Excellent	13 (17.5)	36 (41.4)	10 (13.6)	34 (39.1)	15 (20.3)	39 (44.8)
P value	0.0195		0.0427		0.0001	
20-Minutes Urogram						
Poor	3 (4.1)	1 (1.1)	2 (2.7)	1 (1.2)	6 (8.2)	4 (4.6)
Good	60 (81.1)	63 (72.3)	70 (94.6)	67 (77.0)	60 (81.1)	53 (60.9)
Excellent	11 (14.8)	23 (26.6)	2 (2.7)	19 (21.8)	8 (10.7)	30 (34.5)
P value	0.0255		0.0268		0.0043	
Preparation						
Poor	19 (25.7)	11 (12.6)	10 (13.5)	8 (9.2)	10 (13.5)	9 (10.4)
Good	42 (56.7)	40 (46.0)	54 (72.9)	45 (51.7)	49 (66.2)	39 (44.8)
Excellent	13 (17.6)	36 (41.4)	10 (13.6)	34 (39.1)	15 (20.3)	39 (44.8)
P value	0.0043		0.0001		0.0005	

Notes : P value using Wilcoxon Rank Sum Test
Scale 1-2 = poor, 3-4 = good, 5 = excellent

DISCUSSION

The limitations of this study were : (1) the number of patients in dimethylpolysiloxane group and placebo group was not equal because 17 patients were excluded from the analysis; (2) diet pattern was not evaluated because it was difficult to get such information and conclusion from the questioner; (3) data of Kilovoltages and Milliampere seconds (exposure techniques), as well as the body thickness were not completely recorded in all patients (KV and MAs were given according to the body thickness).

In this study, there were some confounding variables : age, sex, body weight, body thickness, diet pattern, the duration of fasting, and dose of contrast material. These variables confluent the bowel gas pattern or distribution and clarity of urinary tract details.

The distribution of age, sex, weight, level of education, and duration of fasting, showed no statistically significant differences between dimethylpolysiloxane and placebo group. The dose of contrast material was not weight-dependent in this study, and all patients received 20 ml Urografin 76 %.

Using Mann-Whitney U-Wilcoxon Rank Sum W test, there were no extreme interobserver differences. The insignificance only found in interpreting KUB film by the first radiologist. However, in interpretation the urogram and the preparation quality by all three radiologists, it revealed significant difference between dimethylpolysiloxane and placebo group.

Dimethylpolysiloxane is the surface-acting drug that causes the rapid collapse and escape of gas bubbles in the gastrointestinal tract. It changed the surface tension of the mucus-covered gas bubbles, and allowed the smaller bubbles to coalesce. The free gas thus formed was more easily eliminated than were the small tenacious bubbles. The usual adult oral dose is 40 to 80 mg after each meal and at bedtime. It is promoted as an adjunct in the treatment of condition in which gas is the problem, such as reducing gas shadows in radiography.¹² Some authors conclude that this drug is a physiologically inert substance without any evidence of toxicity or side effects.^{9,10,11,12}

Gregersen and Jepsen reported that the use of dimethylpolysiloxane together with laxatives in the preparation of patient for urography has shown a marked reduction in the amount of air in the alimentary tract especially when given in the form of an emulsion.¹⁰ Wiegand found that dimethylpolysiloxane was effective in the preparation of patients for urography. Five tablets dimethylpolysiloxane were given on the day before, followed by an enema containing a tablespoon of dimethylpolysiloxane emulsion early on

the morning of the day when roentgenography was due to take place.¹¹ Ausman demonstrated that this compound was helpful in reducing intestinal gas, clinically and radiologically. Three tablets of dimethylpolysiloxane were administered after each meal and at bedtime on the previous day of the examination, no adjunctive enemas or laxatives were used. Of the 66 intravenous urography, 82 % showed significantly fewer gas shadows.

In our study, we examined the diagnostic quality and gas or feces elimination with the administration of dimethylpolysiloxane before urography procedure.

The results in our study showed no differences with other study previously.

We conclude that the administration of dimethylpolysiloxane as bowel preparation has demonstrated improved diagnostic urogram quality.

REFERENCES

1. Olsson O. An Overview of Uroradiology. In : Pollack HM ed. Clinical Urography. Introduction to Urological Imaging. 1st ed. Philadelphia : WB Saunders Company, 1990; 1-2.
2. Friedenber RM. Excretory Urography in the Adult. In : Pollack HM ed. Clinical Urography. Introduction to Urological Imaging. 1st ed. Philadelphia : WB Saunders Company, 1990; 101-2.
3. Dawson P. A New Look at Intravenous Urography. Australas Radiol., 1988; 309-12.
4. Mellins HZ. Radiology of the Urinary Tract. Urography and Cystourethrography. In : Campbell, ed. Urology. 5th ed. Philadelphia: WB Saunders Company, 1986; 312-3, 316-7.
5. Hattery RR, Williamson B Jr, Hartman GW, LeRoy AJ, Witten DM. Intravenous Urographic Technique. Radiology 1988; 167: 593-9.
6. Lieberman GB. Genitourinary Radiology. In : Siroky MB, Krane RJ, ed. Manual of Urology-Diagnosis and Therapy. 1st ed. Boston : Little, Brown and Company, 1990; 6-7.
7. Kellett MJ, Fry IK. Methods of Investigation. In : Grainger RG & Allison DJ ed. Diagnostic Radiology. 1st ed. New York : Churchill Livingstone, 1986; 1046.
8. Amis ES. Excretory Urography. In : Taveras JM, Newhouse JH ed. Genitourinary Radiology. Radiology Diagnosis Imaging Intervention. 3rd ed. Philadelphia : JB Lippincott Company, 1986; 1-4.
9. Ausman DC. Preparation for Special X-Ray Studies with Simethicone. J Amer Geriat Soc, 1965; 13: 307-12.
10. Gregersen E, Jepsen CL. Dimethylpolysiloxane (Aeropax) Used in the Preparation of Patients for Urography. Ugeskrift for Laeger, 1968; 46: 1960-2.
11. Wiegand G. New Methods for the Control of Meteorism when Preparing Patients for Roentgenography. Medizinische Klinik, 1963; 58: 1152-3.
12. Swinyard EA, Pathak MA. Surface Acting Drugs. In : Goodman Gilman A, ed. The Pharmacological Basis of Therapeutics. 7th ed. New York : Macmillan Publishing Company, 1985; 949.