

Clinical Analysis of a Coaxial Dilator Set Attached to Needle Puncture for Percutaneous Nephrolithotomy*

Evandilson Guenes Campos de Barros^{1#}, Salvador Vilar Correia Lima², Fabio de Oliveira Vilar³,
Eugenio Soares Lustosa⁴, Roberto Santos Lima⁴

¹Master's Program of Post Graduation in Surgery, Center of Health Sciences, Federal University of Pernambuco, Pernambuco, Brazil

²Department of Surgery, Federal University of Pernambuco, Pernambuco, Brazil

³Urology Service of the Hospital das Clinicas, Federal University of Pernambuco, Pernambuco, Brazil

⁴Member of the Brazilian Society of Urology, Recife, Brazil

Email: [#]evandilsonguenes@gmail.com

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ABSTRACT

Introduction: Percutaneous approach to the kidney is a very useful alternative in renal surgery which minimizes the morbidity of a variety of procedures. **Objectives:** To evaluate the efficacy, practicality of a reusable system of metallic coaxial dilator coupled to a special puncture needle to perform lumbar puncture and dilation of the percutaneous tract. **Methods:** A randomized experimental study was carried out involving 50 individuals. These patients were randomized as follows: Group 1 had the procedure performed with the conventional disposable Amplatz set traditionally used for this procedure. Patients in Group 2 were operated utilizing the new reusable coaxial set specially designed for this purpose. The following parameters were measured to compare the 2 groups: sex Corporeal Mass Index (CMI), Pre and postoperative hematocrit and hemoglobin. Time interval between the puncture, dilation and access to the renal pelvis and insertion of the nephroscope were also analyzed. **Results:** There was no statistical difference between the 2 groups concerning hematocrit and hemoglobin changes when comparing pre- with postoperative period. Patients in Group 2 required a significant lower time between puncture and final access to the upper collecting system. **Conclusion:** The new coaxial dilator set showed to be as safe as the conventional Amplatz set with the advantage of reusability and decrease of tract dilation time.

Keywords: Percutaneous Nephrolithotomy; Metallic Coaxial Dilator; Kidney Stone

1. Introduction

Urinary lithiasis is one of the most common diseases affecting the urinary tract with an incidence rate ranging from 5% to 15% according to world literature [1]. Official data from Brazilian health system indicate that over 300.000 hospital admissions occurred between January and May 2012. From this group, 8.79% were related to urinary stone disease [2].

The removal of urinary stones has evolved significantly in the last 25 years since the introduction of percutaneous nephrolithotomy (PNL) ureterorenoscopy (URS) and extracorporeal shockwave lithotripsy (ESWL). The sophistications introduced to these equipments and different sources of energy to destroy stones gave a new

insight to the adequate definition of the type of treatment to be applied according to stone size and location and as such represents a significant advance in the treatment of this disease [3,4]. In an attempt to reduce costs and time to perform percutaneous approach to the kidney without increasing morbidity to the procedure, we propose a new reusable dilating system, which significantly decreases these items and offers new possibilities in performing percutaneous renal surgery. In this procedure, a path is created for percutaneous removal of stones by using an association of principles already used for this purpose. On the other hand, serial or telescopic, pneumatic dilators have shown to require greater surgical time and increased incidence of bleeding [5]. Most surgeons prefer to use sequential dilators to create access to the kidney.

With the development of more sophisticated devices, it is possible to promote a gateway to the kidney with

*I declare that all information shown in this study are results of our work and there is no plagiarism.

[#]Corresponding author.

lower diameter (11 - 18 French) and consequently less morbidity to the patient [6].

The aim of the present study is to test the efficacy and practicability of this new reusable set of metallic coaxial dilating system in comparison with the disposable system normally used in clinical practice (Figures 1 and 2). As the basic principles of the surgical technique have not been modified, an experimental trial of the procedure was not performed in animals.

2. Patients and Methods

A randomized clinical study, involving 50 patients from our outpatient clinic suffering from nephrolithiasis with surgical indication for percutaneous nephrolithotomy was carried out to prove the feasibility of this method. Patients were informed about the objectives of the study and invited to participate.

Patients age ranged between 20 and 60 years and were

PN - Puncture Needle
CDS - Coaxial Dilating Set



Figure 1. Special extra length puncturing needle and coupled dilating set.

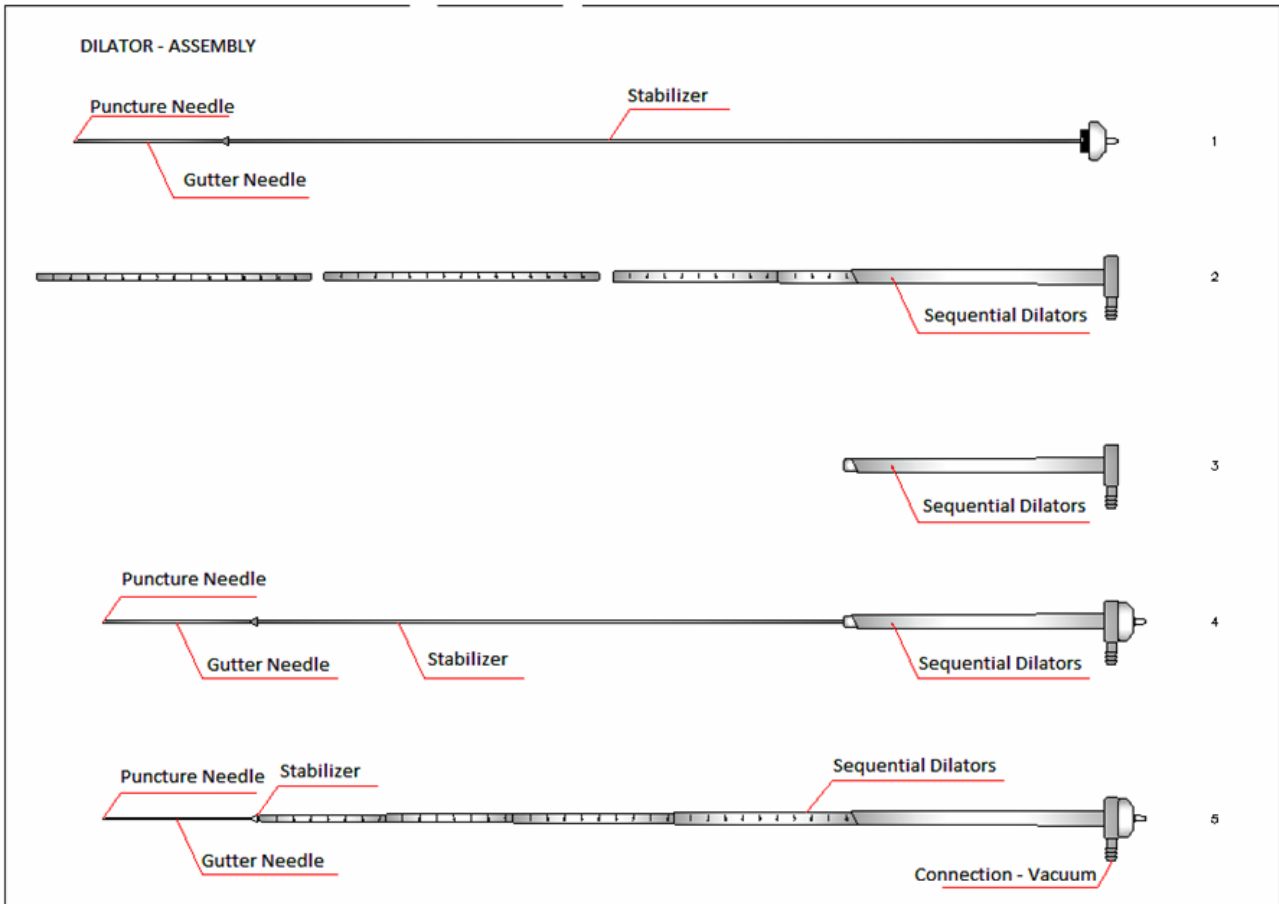


Figure 2. Schematic drawing of the dilating set and its coupling and operating way.

randomized into two groups: Group 1: patients with medical records ending in even numbers who underwent PNL technique using conventional disposable sequential Amplatz dilators. Group 2: patients in the records ending in odd numbers who underwent the procedure use the new coupled coaxial dilators.

Two main parameters were analyzed: time spent between puncturing and dilating the tract and insertion of the nephroscope confirming access to the renal collecting system; blood loss was evaluated by checking HT and HB in the pre-operative period, 24 hours after the procedure and at discharge. Possible complications of dilation process—like renal pelvis and renal pedicle vessels injury, puncture of solid organ or bowel were also analyzed.

Statistical analysis was divided into three steps according to the objectives previously established: Comparison of the groups according to sex, age, BMI, Hb and Ht; comparison of groups of time dilation; intragroup comparison (pre X post) and between groups as related to Hb and Ht.

To compare the distributions by gender we used the chi-square test, and the Student *t* test was applied to compare quantitative variables (age, BMI, Hb and Ht) between groups.

The nonparametric Mann-Whitney test was used to compare the groups related to time spent to dilation due to lack of normality of this variable.

To evaluate the differences between both groups (experimental standard X) and between times (pre X post) regarding the variables Ht and Hb, we used a model of analysis of variance (ANOVA) with repeated measurements.

The study was approved by the Ethics Committee for Clinical Research of the Institution.

3. Results

The results are illustrated in the **Tables 1** and **2**, which shows that there was no statistically significant difference between the groups as related to variables, *i.e.*, the groups can be considered homogeneous for this purpose.

There is a statistically significant difference between groups ($p < 0.05$). The time dilation of the experimental group was lower than the standard group.

This analysis evaluated the effects of group, time effects and the interaction effects between groups and time. Because the interaction was not considered statistically significant ($p > 0.05$) for both the Hb and to the Ht, we evaluated the effect of group (collectively for all times) and end time (jointly for both groups).

Analyzing the results of ANOVA, it can be stated that:

Hb: no significant difference between groups ($p = 0.403$) in the two periods. When analyzing intra-group comparison (pre X post) it was found that there was a significant

reduction in pre and post results in both groups ($p = 0.007$).

Ht: no significant difference between groups ($p = 0.204$) in the two periods. When analyzing intragroup comparison (pre X post), it was found that there was a significant reduction from pre to postop results in both groups ($p = 0.009$).

There was only one complication in one patient in Group 1 (Amplatz dilators). An inadvertent perforation of the renal pelvis, leading to the development of ascites urinosa was found. There were no complications in the group using the new coaxial dilator. The presence of this unique complication was not statistically significant in the study.

4. Discussion

There are various techniques described to perform access directly to the collecting system, the most frequent being Amplatz dilators, coaxial Alken dilators and balloon dilators. Such techniques have similar complication rates [7].

The ideal technique for percutaneous access must have acceptable complication rates, promote easy access to the renal collecting system and at the same time provide low economic impact. The number of kidney punctures required to perform an adequate nephrostomy tract is directly related to bleeding in percutaneous nephrolithotripsy [8].

Table 1. Results of the analysis of homogeneity between groups.

| Variable | Groups | | p-value |
|-------------------------|-------------|--------------|---------|
| | Standard | Experimental | |
| Females | 13 (52%) | 13 (52%) | 1.00 |
| Age (years) - Mean (SD) | 42.3 (11.5) | 37.6 (10.9) | 0.146 |
| Minimum - Maximum | 24 - 66 | 22 - 58 | |
| BMI - Mean (SD) | 28.3 (4.5) | 29.6 (4.1) | 0.282 |
| Minimum - Maximum | 21.6 - 41.0 | 23.1 - 38.2 | |
| Hb - Mean (SD) | 13.9 (1.4) | 13.76 (1.2) | 0.387 |
| Minimum - Maximum | 11.4 - 17.5 | 11.7 - 16.4 | |
| Ht - Mean (SD) | 42.0 (4.2) | 40.4 (3.1) | 0.134 |
| Minimum - Maximum | 35 - 51 | 35.8 - 46.5 | |

SD = standard deviation; BMI = body mass index.

Table 2. Results of the comparison between the groups with respect to time dilation.

| Dilation Time (minutes) | Groups | | p-value |
|-------------------------|------------|--------------|---------|
| | Standard | Experimental | |
| Median | 12 | 2.2 | <0.001 |
| P25 - P75 | 8.6 - 12.5 | 1.5 - 2.4 | |

P25: Percentile 25, P75: Percentile 75.

The preference for the comparative study between the coaxial dilator and coupled sequential dilators refers to the failure rate of inflatable dilators (17%). This rate rises to 25% when applied to patients with previous surgery [9]. Pneumatic dilators have not shown better results than the Amplatz dilators concerning decreased surgical time and decreased postoperative complications and a higher cost [10].

According to data collected, there was homogeneity between groups A and B, related to gender, age, body mass index (BMI), and hematological: hemoglobin (Hb) and hematocrit (Ht).

The concern about having homogeneous groups refers to the possibility of difficulty in performing the procedure on specific groups, mainly related to BMI. This confirmation supports the reduction rates of research biases. Kessarar *et al.* [11] analyzed 2200 percutaneous renal procedures and stated that it was not a risk factor for renal bleeding: age, sex, number of punctures renal and procedure duration.

The measurement of efficacy in performing the nephrostomy tract was defined as the time required establishing the path after percutaneous puncture of the collecting system and insertion of the nephroscope. The time dilation was lower in the group that used the new coaxial dilator: The mean time spent with the standard technique 12 was minutes, and 2.2 minutes with the new set ($p < 0.001$). This can be explained by the elimination of some steps in the dilating process, which leads to savings in time such as switching stabilizer using a puncture needle as a guide; stabilizer safety valve "stop", which prevents the progression of the device in addition to the limit established by the surgeon, decreasing complication rates; sequential dilators and coupled to the system in monoblock; stabilizer removed en bloc and dilator set, maintaining 30 French (F) sheath and guide wire.

The level of bleeding caused by the dilator was similar in both groups, as shown by comparing drop in Hb and Ht between groups and within groups. No patient in both groups required blood transfusion. These data confirm reports of the literature [12]. Michel *et al.* [13] in a series of 315 cases reported 17.5% of blood transfusion.

Bleeding is the most common complication and is associated with the number of punctures, stone volume and diameter of the surgical material [8]. All patients underwent only one puncture per treatment session, the diameter of the material used was 30 F in the two groups. As described before the bleeding rates are similar to the reports by others [13].

The overall rate of complications in percutaneous nephrolithotomy can reach up to 83% [14]; however, the vast majority of these complications are minor, such as bleeding or fever without further repercussions. Major

complications occur between 0.4% - 4.7% to sepsis and 0.6% - 4% to renal bleeding needing surgical intervention [6]. In the present study, one lesion of the renal pelvis was observed in the control group. No complications were seen in the study group.

When considering costs to perform percutaneous nephrolithotomy, although no specific studies were performed specifically considering this item the new set of dilators promotes significant savings according to the literature without increasing the surgical risks to patients and maintaining similar efficacy [15].

5. Conclusion

Data obtained in the present study support the idea that a reusable coaxial metallic set may represent a feasible option in the percutaneous approach to the kidney and produces significant savings especially for institutional use without increasing surgical risks.

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List of Abbreviations

PNL: Percutaneous nephrolithotomy
 URS: Ureterorenoscopy
 ESWL: Extracorporeal shockwave lithotripsy
 BMI: Body mass index

Hb: Hemoglobin
 Ht: Hematocrit
 ANOVA: Analysis of variance
 F: French