## Endourology

## Does the Size of Ureteral Stent Impact Urinary Symptoms and Quality of Life? A Prospective Randomized Study

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## Abstract

*Objective:* To evaluate the effect of stent diameter on patients' symptoms and quality of life (QoL) by using dedicated questionnaires.

*Methods:* We prospectively enrolled 34 patients with unilateral ureteral obstruction due to urinary stone undergoing to ureteral stenting (17 pts with 4.8 F and 17 pts with 6 F) before treatment of stone disease. Twenty-one patients with lower urinary symptoms from other causes were used as a control group. Two questionnaires, one on QoL and another on stent specific symptoms, were administered to patients one week after stent positioning and 4 week after removal.

**Results:** There was a significant association between stent state and answers on pain and discomfort on QoL questionnaire. A high percentage of patients reported anxiety and depression associated with the stent. Similar significant association was found between stent state and urinary symptoms and pain. No differences in QoL and urinary symptoms and pain were detected using stents with different size.

*Conclusions:* Ureteral stents are invariably associated with urinary symptoms and impaired QoL. We did not find any difference between stent with different size, whereas there was a tendency for stent with smaller diameter to dislodge more often.

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## 1. Introduction

Ureteral stenting has become a part of routine clinical practice in the treatment of ureteral obstruction. Uncontroversially, side effects and complications reported have increased compared to the past and today patients morbidity associated with stents have been identified as major problem [1,2].

Indwelling ureteral stents are considered to produce significant discomfort and it is also recognized that the degree of discomfort varies among patients. In spite of improvements in stent designs and composition, objective and structured in depth assessment of the impact of the stent on patient's quality of life (QoL) has been only recently performed [3,4] and represent an important measure in clinical practice [5].

The assessment of the urinary symptoms caused by stents is not easy using clinical measures. Moreover, it has been demonstrated that validated questionnaires, commonly used to assess QoL, can have levels of precision that equal or exceed clinical measures [6].

The most common questionnaire to assess lower urinary tract symptoms (LUTS), as the International Prostate Symptom Score (IPSS), is not condition specific and



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does not evaluate the specific impact of the stent on patients' symptoms.

We report our experience on the evaluation of symptoms related to indwelling double pigtail stents and their impact on patient's QoL, based on different stent diameters, using a validated QoL questionnaire and a stent symptom specific questionnaire.

## 2. Matherials and methods

#### 2.1. Study population

Overall, we prospectively considered 34 patients with unilateral ureteral obstruction due to urinary stone undergoing ureteral 28 cm polyurethane stent positioning before treatment of stone disease. 17 patients (group A) underwent a 4.8 F, while in the other 17 (group B) a 6 F stent.

The criterion for entry into the study was unilateral placement of a double pigtail ureteral stent for urinary calculi that remained indwelling for at least 7 days. Pregnant women, patients with presence of bilateral obstruction, obstruction due to malignancy and additional procedures were excluded from the study. The stents were placed under local anaesthesia and i.v. sedation and the choice of the stent diameter was obtained by randomization tables in a single-blind fashion. A plain abdominal radiograph was routinely used to verify correct placement of the stent and dislodgement as a cause of related symptoms [7]. Patients returned a week later for shock wave lithotripsy.

Twenty-one patients with LUTS (mean age 48 years, 10 males, 11 females) were used as a control group. This choice meant to confirm the common belief that that the stent state has a higher negative impact on patient's QoL than other causes of LUTS.

Two questionnaires, one on the general health status (EURO QoL EQ-5D) [8], validated in Italian, and another specific on the stent related morbidity, adapted by the ureteral stent symptoms questionnaire (U-SSQ) as described by Joshi et al. [4], were administered between 7 and 14 days after the stent positioning procedure and again 4 weeks after stent removal.

#### 2.2. QoL assessment

The aim of choosing Euro QoL was to identify whether there were differences in gross defect in the physical and psychosocial well being of the patients.

This questionnaire is a generic health status instrument with five domains each of health dimension (mobility, self care, usual activities, pain/discomfort, anxiety/depression) scaled from one to three score (some, moderate, extreme problems). The result is presented as the proportions of the population reporting level 1 (no problems) level 2 (some problems) and level 3 (extreme problems) for dimension. For the data analysis we considered the sum of proportions of the reported level 2 and 3 problems for each domain.

Moreover, a visual analogue scale (VAS) has been used to generate a self rating of health state score on a vertical 20 cm scale having numeric values of 100 and 0.

### 2.3. Stent specific symptoms assessment

The stent specific questionnaire, whose development was based on a literature review and also included opinion of urologists based on a day-by-day management of such patients, consisted of questions assessing urinary symptoms (4 items – dysuria, hematuria, urgency and frequency), pain (site and duration) and usual problems in day to day life (with 4 items – symptoms of urinary infections as pain on micturion and/or fever, need of pain killers, need of antibiotics and problems of dislodged stent). The answer to these questions were based on a four point rating scale.

The scoring system for the questionnaire consist of a simple sum of the scores for individual questions in each section. There is no single score for the whole questionnaire and each section had a summary (index) score with the high scores indicate worse outcomes.

#### 2.4. Statistical analysis

The stent related impairment of QoL and urinary symptoms were the primary end-point of the study. A difference of 50% was considered to be a meaningful difference. This was based on inhouse audit data and literature analysis [4]. It was determined that stent state would be defined as responsible of the QoL and symptoms impairment should its use decrease the expected EQ VAS. To detect a difference of this magnitude with a power of 80% and a significance level of 5%, about 15 patients per arm (stented versus control groups) were required. Stratification factors included age and gender.

Descriptive statistics was used to assess the differences between the results both with the stent in situ and after removal. Paired t tests were used for the studies with Euro QoL and stent specific questionnaires.

## 3. Results

The groups were comparable in respect of sex, age, stone size and location (Table 1).

In the evaluation of the general health, EURO QoL analysis revealed an association between the stent state and responses regarding the different domains, with pain/discomfort being the most bothersome significant feeling for the patients when compared with the results obtained from the control group with LUTS (p Value = 0.02 and p Value = 0.019). However, no differences were found when comparing the two stented group (p Value = 0.073) (Fig. 1).

EQ-5D self rating of VAS QoL at 1 week assessment revealed a significant difference between group A and

| Table 1  |             |      |
|----------|-------------|------|
| Patients | demographic | data |

|                          | Group A<br>( <i>N</i> = 17) | Group B<br>( <i>N</i> = 17) | Control $(N = 21)$ |
|--------------------------|-----------------------------|-----------------------------|--------------------|
| Mean age (range)         | 47.3 (29–71)                | 50.1 (33-68)                | 48 (27–66)         |
| M/F                      | 7/10                        | 6/11                        | 8/13               |
| Stone location           |                             |                             |                    |
| Proximal                 | 2                           | 3                           |                    |
| Medial                   | 6                           | 4                           |                    |
| Distal                   | 9                           | 10                          |                    |
| Stone size (mm $\pm$ SD) | $9.4\pm3.1$                 | $9.7\pm2.7$                 |                    |

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