Side-Effects of Polyurethane Ureteral Stents with or without Hydrogel Coating in Urologic Pathology

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Ureteral stents represent one of the most utilized medical device in urology, as a minimally invasive alternative to preserve urine outflow. The ideal ureteral stent which combines long-term efficacy with a very low rate of side effects is still missing from the urologist armamentarium. The main material for ureteral stents production is polyurethane. In order to improve the side-effects and complications of polyurethane stents, special coatings were developed. The aim of this study is to evaluate short-term side-effects and complications of different polyurethane stents with or without coating used in urologic field.

Keywords: ureteral stents, medical device, polyuretane

From their first use by Paul Zimskind in 1967, ureteral stents had continuously evolved and extended their use, in our days becoming one of the most intense utilised urinary devices. Current indications for stent placement include relief of ureteral obstruction whether the cause is intrinsic (from calculus, clot or urothelial carcinoma) or extrinsic (from external compression or mass effect such as lymphadenopathy or pregnancy), and for maintening the ureteral patency after surgery or trauma. [1]

Ureteral stents are associated with a high rate of side effects, according to some authors up to 80%, including hematuria, irritative voiding symptoms, flank pain especially during micturition, recuse libido and reduce work capacity [2].

In addition to this side-effects the ureteral stents can present complications such as encrustation and urinary infections, than can lead to low tolerance of the stent and a poor quality of life for the patients [2].

The low cross-linked polyurethanes has better mechanical properties and the content of the cross-linking has a very significant effect on these properties, being the material of choice in the study of new ureteral stents designs when adding the cost [3].

Experimental part

In the present study we analized the side effects and complications of polyurethane ureteral stents with or without hydrogel coating or antireflux valve.

We have analized 431 consecutive patients, between 2012-2016, who benefit from an urologic intervention that required the placement of an ureteral stent. For a better assessment of the complications we have evaluated only the patients that required the stenting for more than a mounth. All patients were asked to complete a questionnaire that included a scale from 1 (no symptoms) to 5 (worst severity symptoms) regarding dysuria, flank pain during micturition, urgency, frequency, pelvic pain. All stents were removed by cystoscopy, and we didn't have any case of stent migration or spontaneous dislodgement. We performed an urine cultures for all patients with 1-2 hours before removing the stent. For the second group of patients we conducted a microscopic evaluation of the stent using a microscope in order to evaluate the presence or absence of encrustation (fig.1, .2). Patients who were enable to complete the questionnaire, those with malignancies and those with preoperative positive urine cultures were excluded.

Fig.1 Radiological aspect of ureteral stone stent

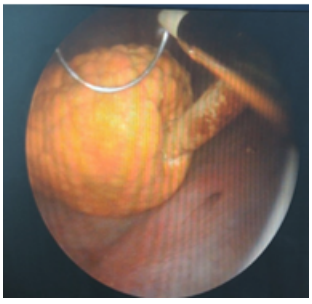

Fig.2 Cystoscopy aspect of stone stent

Stent length	Dysuria (%)	Urgency (%)	Frequency (%)	p
24 cm	47.4	53.7	55.8	ns
26 cm	51.2	58.1	54.3	ns
28 cm	50.9	55.6	59.1	ns

Table 1

ns- not statistically significant

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Stent size	Dysuria (%)	Urgency (%)	Frequency (%)	p
6 Ch	21.7	47.2	24.1	p<0.03
7 Ch	34.2	51.3	33.9	p<0.03
8 Ch	59.8	56.8	62.3	p<0.03

Table 2

Urologic procedure	All patients	Stent with hydrogel coating	Stent without hydrogel coating
Endopyelotomy	32	18	14
Open ureterolythotomy	2	1	1
Laparoscopic ureterolythotomy	6	4	2
Open pyeloplasty	7	3	4
Laparoscopic pyeloplasty	34	20	14
Uretero-vesical reimplantation	17	11	6
Ureteral suture after abdominal surgery (iatrogenic injury)	6	3	3
Total	104	60	44

Table 3

The statistical analysis of this paper was done by using chi-square test, , the Fischer exact test. A p value <0.05 was considered statistically significant.

Results and discussions

The mean age of patients was 47.6 years (range 18-84 years) and 57.3% (247/431) were men. Stents were placed into left ureter in 66.58% (287/431) patients. The most common symptoms were dysuria, urgency and urinary frequency, who were present in 50.1%, 56.3% and 57.5% of patients.

When comparing dysuria, urgency and urinary frequency with the length of the stents the results were comparable as showed in table 1.

Same situation was when we compare the type of the stent with the low urinary tract symptoms determined by the presence of the stent.

There was a clear statistical correlation when comparing the symptoms with the size of the stents, with low dysuria and frequency rate for 6 Ch stent (21.7% and 24.1%) compared to 7 Ch stent (34.2 and 33.9%) and 8 Ch stent (59.8 and 62.3%) with $p<0.03$ (table 2).

When comparing flank pain during micturition with stent length and size there were no differences, but when comparing it with stent type, there was a low rate of patients with flank pain in the antireflux valve group (7.2% vs. 20.3% vs.21.8%).

Macroscopic hematuria was present in 243 patients (56.3%) with no correlation to the stent type, length or size.

Overall 104 patients required ureteral stenting more than 1 mouth but not more then 3 mouths and the urologic procedures are listed in table 3, alongside the type of the ureteral stent.

The rate of encrustation for the entire group was 38.4 %. When taking into account the type of stent used we observed a difference in favor of the hydrogel coating ureteral stent, 31.6% (19/60) vs. 47.7% (21/44). We didn't have cases of stent fragmentation or impossibility of retrieval. According to S. Oprea et al. the variation of the hard segment structure in the polymer matrix may also have affected the surface properties[6], that can lead to new materials in developing ureteral stents with a low encrustation rate.

Urine culture was positive in 87 patients (20.1%), the most common pathogen was E.coli in 42 p, with disregard of stent type, size or length.

Conclusions

Polyurethane ureteral stents with hydrogel coating represent a good alternative to polyurethane stents without coating, with lower side-effects rate and complications. When adding the anti-reflux valves the side-effects rate is even lower, but still high when compared to general population.

Urothelial hyperplasia, stent encrustation, ureteral mobility, response to ureteral intraluminal foreign-body stimuli and also the bladder response to the stent are the most important factors to take into account into developing a new generation of ureteral stents.

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