

Immunoactive Prophylaxis Protocol of Uncomplicated Recurrent Urinary Tract Infections In A Cohort of 1104 Women Treated With Uromune® Vaccine.

834



Ramírez Sevilla C¹ , Gómez Lanza E² , Puyol Pallàs M¹

1. Fundació Hospital Sant Joan de Déu de Martorell, Barcelona
2. Hospital de Sant Joan Despí Moisès Broggi, Barcelona. Spain

Aims of study

Analyze the efficacy of Uromune® vaccine to prevent uncomplicated recurrent UTI and perform a follow-up protocol.

Study design, materials and methods

STUDY DESIGN	VARIABLES
Prospective	Age
Descriptive	Number of UTIs
Multicenter	0, 3, 6 and 12 months
Jan 2011 – May 2023	Groups of age
n=1104 women	Months of the year
rUTI	Vaccine / autovaccine
Uromune® vaccine / autovaccine	
Follow-up: 3, 6 and 12 months	*SPSS v 15.0

EFFICACY of Uromune®: presence along follow-up of 0, 1, or 2 UTI positive urine cultures after the end of treatment.

EXCLUSION CRITERIA
Neuro-genic bladder
Symptomatic urinary calculi
Nephrostomy, ureteral pigtail and urethral catheter
Moderate to severe urinary incontinence defined as the presence of three or more one-hour pad tests equal to or greater than 50 cc along 24h
Lower urinary tract symptoms (LUTS) in progression defined as patients with IPSS greater than 20 despite medical treatment with alpha blockers, 5-alpha-reductase inhibitors or both combined
LUTS and cystocele with postvoid volume greater than 100 ml
Patients with urinary diversion

GROUPS OF STUDY	% UTI at baseline
GROUP 1 (65,2%)	3-4
GROUP 2 (34,8)	>=5

✚ Results after vaccination between both groups were compared, and a follow-up protocol was performed.

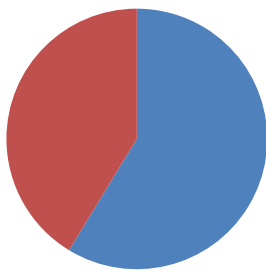
Results

Bacteria	%
<i>E coli</i>	64,3
<i>K pneumoniae</i>	24,3
<i>P vulgaris</i>	5,9
<i>E faecalis</i>	3,5
<i>P aeruginosa</i>	1,4
<i>C koseri</i>	0,5

✚ Median age: 72

Years	% UTI
<30	1,9
30-50	5,4
50-70	26,5
>70	66,1

Autovaccines: 41,3% (456)



Vaccines: 58,7% (648)

Month	Jan	Feb	March	April	May	June	July	Aug	Sep	Oct	Nov	Dec
% UTI	6,8	11,3	12,3	11	8,6	5,3	7,4	4,8	7,2	10,1	8,1	7,1

Side effects (1,36%,15)
Dry mouth 8
Gastritis 4
Sickness 3

Baseline	3	4	5	6	7	8	9	10
% UTI	40,8	24,5	19	9,8	4,1	1,6	0,2	0,1

✚ No one abandoned treatment
✚ No side effects with autovaccines

Months	0 UTI	1 UTI	2 UTI	3 UTI	4 UTI	5 UTI	6 UTI	7 UTI	EFICACCY
3	41,5	30,5	19,7	6,7	1,4	0,1	0,1	-	91,7
6	26	32,5	23,8	12,9	3,9	0,5	0,3	0,1	82,3
12 (n=611, 55%)	9,8	27,5	20,3	25,5	13,6	2,6	0,5	0,2	57,6

EFICACCY	3months	6 months	12 months
Vaccines	95,8	88,4	56,1
Autovaccines	85,7	73,6	60,2

p<0,05

EFFICACY	Group 1 (< 5 UTI)	Group 2 (>= 5 UTI)
3 months	98,2%	87,6%
6 months	92,5%	69,4%
12 months	62,1%	40,2%

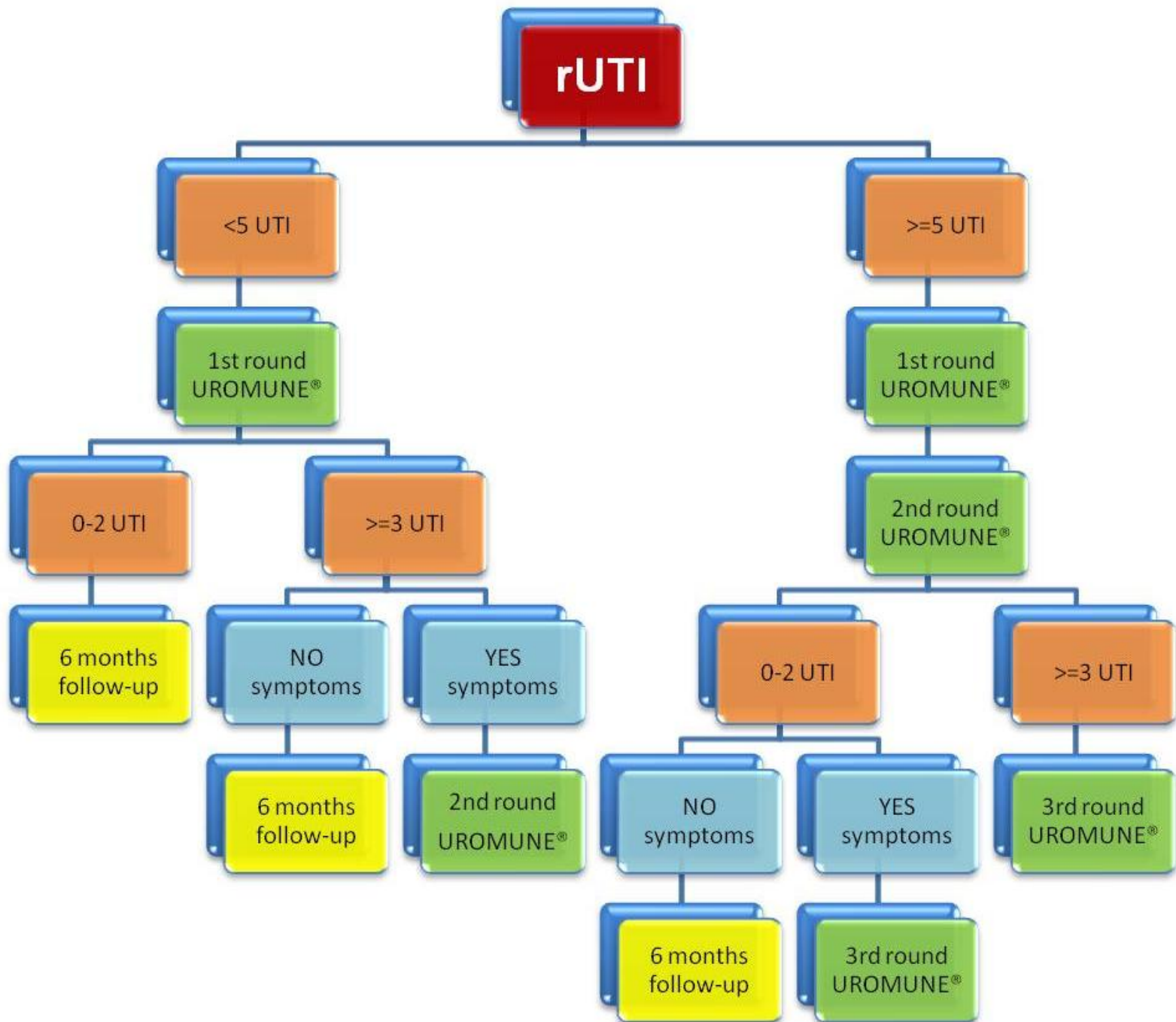
p<0,05

Interpretation

✓Patients at baseline with less than 5 UTI will have better result with Uromune®. That is the reason to propose a new protocol in the immunoactive prophylaxis of uncomplicated recurrent UTIs.

✓Patients with less than 5 UTI at baseline will receive 1st round of vaccine. Result: if 0-2 UTI, clinical follow-up and urine culture at 6 months will be the best option. If 3 or more UTI were presented without symptoms, follow-up at 6 months will be mandatory, and if patients had 3 or more UTI with symptoms 2nd round of revaccination will be necessary.

✓Patients with 5 or more UTI at baseline will follow 2 rounds of vaccine initially. Result: if 0-2 UTI and absence of symptoms, clinical follow-up with urine culture at 6 months will be the best option. If 0-2 UTI with symptoms, patients had to re-vaccinate on 3rd round. Result: if 3 or more UTI after second round, re-vaccination (3rd round) is recommended.



Immunoactive prophylaxis protocol with Uromune® in uncomplicated recurrent UTI

Conclusions

- Immunoaaactive prophylaxis with Uromune ® offers high efficacy in patients with uncomplicated recurrent UTI.
- The follow-up protocol with Uromune ®, according to the number of UTI at baseline, the result of urine culture along follow-up and the presence or not of symptoms, can be very useful to improve the quality of life of our patients.
- Whenever available, polyvalent vaccines are recommended because can offer better results than autovaccines.

References

1. Cueto M, Aliaga L, Alós, JI, Canut A, Los-Arcos I, Martínez J.A et al. Executive summary of the diagnosis and treatment of urinary tract infection of the Spanish Society of Clinical Microbiology and Infectious Diseases (SEIMC). Enferm Infecc Microbiol Clí. 2017;35:314–20.

2. Ramírez Sevilla C, Gómez Lanza E, Llopis Manzanera J, Cetina Herrando A, Puyol Pallàs JM. A Focus on Long-Term Follow-Up of Immunoprophylaxis to Recurrent Urinary Tract Infections: 10 Years of Experience with MV140 Vaccine in a Cohort of 1003 Patients Support High Efficacy and Safety. Arch Esp Urol. 2022;75(9):753-7.

3. Lorenzo-Gómez MF, Foley S, Nickel JC, García-Cenador MB, PadillaFernández BY, González-Casado I et al. Sublingual MV140 for Prevention of Recurrent Urinary Tract In-fectiions. NEJM Evid 2022;1:660.