PHYSION®

SINGLE INTRAVESICAL INSTILLATION OF EMDA-MITOMYCIN BEFORE TURBT

DRUG SOLUTION

Dilute 40 mg of mytomicin in:

- 100 ml bidistilled water if excipient is sodium chloride;
- 100 ml Sodium Chloride 0.9% if excipient is urea or mannitol

PARAMETERS

CATHETER-ELECTRODE	CE-DAS® UROGENICS®/ S – Version PH00971301
CURRENT STRENGTH	23 mA / PULSED
TIME OF TREATMENT	20 min
POLARITY	POSITIVE (+)
RISE-RATE	40 µA/sec

ELIGIBILITY

- Patients with established endoscopic diagnosis of urothelial carcinoma of the bladder, primary and clinically non-infiltrating the muscular tunic
- Patients over the age of 18
- ECOG performance status between 0 and 2
- Hematology framework within the limits of the standard
- Renal function within the limits of the norm
- Liver function within the limits of the norm

NEOADJUVANT TREATMENT

- Before the intravesical treatment the eligible patients must undergo:
  - renal and bladder ultrasound
  - cystoscopy
  - and/or urinary cytology on 3 samples taken for 3 consecutive days

- Dilute 40 mg of mytomicin in:
  - 100 ml bidistilled water if excipient is sodium chloride;
  - 100 ml Sodium Chloride 0.9% if excipient is urea or mannitol.

- Perform single mytomicin instillation with EMDA 30/60 minutes before spinal or general anesthesia for endoscopic resection of bladder cancer.

- At the end of the treatment the mitomycin solution is evacuated by gravity through the catheter / electrode that is removed.

- The patient is then subjected to anesthesia and endoscopic resection of bladder cancer.

- After the operation, a continuous bladder wash is applied for 8-18 hours to avoid clots or retention with related complications.

- Once the definitive histological diagnosis is obtained, the adjuvant treatment is established based on the pathological staging and the risk classification in accordance with the EAU guidelines.

ADJUVANT TREATMENT

LOW RISK PATIENT

No intravesical adjuvant treatment and follow-up with ultrasound, cystoscopy and urine cytology every 3 months for the first year.

INTERMEDIATE RISK PATIENTS

Intravesical chemo-prophylaxis with EMDA /MITO: induction (6/8 weekly instillations x 6/8 consecutive weeks) and maintenance (3 monthly instillations, cycle to be repeated 2 times); follow-up: ultrasound, cystoscopy and urine cytology every 3 months for the first 2 years.

HIGH RISK PATIENTS

Intravesical chemo-immuno-prophylaxis with BCG and EMDA /MITO: induction (9 weekly instillations: BCG + BCG + EMDA /MITO, cycle to be repeated 3 times) and maintenance (9 monthly instillations: EMDA /MITO + EMDA /MITO + BCG, cycle to be repeated 3 times) Follow-up: ultrasound, cystoscopy and urine cytology every 3 months for the next 2 years.

EXCLUSION CRITERIA

- Allergy and / or intolerance ascertained by the mytomicin
- Presence of pacemakers or other active implantable medical device
- Non-urothelial bladder carcinomas
- Previous or concomitant diagnosis of urothelial carcinomas of the high urinary tract and prostatic urethra
- Bladder capacity less than 200 ml
- Untreated concomitant urinary infections
- Severe systemic infections (sepsis)
- Urethral malformations or stenoses that can prevent bladder catheterization and endoscopic procedures
- Pregnancy

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