METHOD FOR THE EARLY DIAGNOSIS OF UROPERITONEUM

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Invention

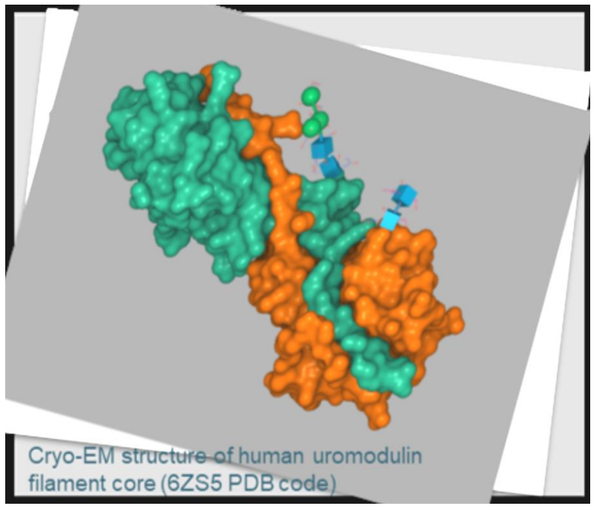
The collection of urine in a patient's peritoneal or retroperitoneal cavity, called **Uroperitoneum**, can occur due to traumatic or iatrogenic events, as a result of **spontaneous rupture due to neoplasia or chronic inflammation** in the kidney, ureter, bladder, or proximal portion of the urethra, and as a complication of major urologic procedures. Uroaddomen has serious consequences that compromise patient life. Indeed, the **presence of urine in the abdominal cavity** triggers an inflammatory cascade and a series of electrolyte disturbances that have a major impact on cardiac and renal function. Uroaddomen causes dehydration, azotemia, hyperkalemia and metabolic acidosis.

The innovative method to diagnose uroperitoneum involves determining the **concentration of a biomarker, Uromodulin, in a sample taken from abdominal drainage**.
The method enables early diagnosis with the assay of uromodulin, overcoming the limitations shown by diagnostic techniques in use to date represented by:

- the creatinine assay, which has proven to be an insensitive and reliable marker only in an advanced condition of uroperitoneum, i.e. when urine leakage in the abdomen is very profuse;

- computed tomography (CT) scan of the abdomen, a diagnostic tool that involves moving the patient, usually bedridden in the post-surgical phase to the intensive care unit, and administering iodinated contrast medium that exposes patients to increased radiological risk.

Drawings
& pictures



Industrial applications

The application of the proposed technology and method is definitely medically relevant, useful to maximize the **early diagnosis of Uroperitoneum**, in order to promptly implement the best therapeutic strategy and achieve the best outcome for the patient.

The method is useful in the context of **clinical analysis and in surgical wards**, predicting to correlate the concentration of **Uromodulin present in the abdomen to the early diagnosis of the pathological condition**, particularly in urological patients who are in a post-operative phase after urological surgery or in intensive care.

The creation of a **Point-of-Care Test (POCT)** would have potential operational advantages in the hospital setting:

- decision-making processes would be much faster,
- operational and treatment time in the postoperative period would be reduced.

In view of the digitization of health services, the development of such devices could be considered to ensure results are obtained immediately by exporting them to an electronic medical record. Thus, results can be shared easily and instantly with all members of the medical team through a software interface.

Possible developments

The concentration of uromodulin is determined by a common ELISA assay: it is infinitesimal (<50 ng) in abdominal drainage samples under physiological conditions, while it reaches measurable concentrations from the early stages of uroperitoneum.

The studies evaluated the high sensitivity and specificity of the diagnostic method for indicating the presence of urine in the abdomen. In addition to the **ease of measurement** of the biomarker in biological samples and the **limited invasiveness**, as samples can be quickly taken from the drainage systems of patients under postoperative conditions, the invention allows rapid association of the presence of uromodulin with a pathological situation.
The method requires n**either reagents nor particularly expensive machinery**.

The studies conducted continue toward the implementation and validation of the proposed method and aim to create a **Point-of-Care device** to retrieve clinical data more quickly and operate strategically.

The inventors are interested in future collaborations to increase biological results acquisition and to develop an innovative device based on the patented method. With this purpose, the team can take into consideration a possible licensing of the patented invention to develop a commercially available device.

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