RENAL CANCER DETECTION WITH A NEW NON INVASIVE DIAGNOSTIC TOOL (TRIMprob™): A SCUP* PILOT STUDY

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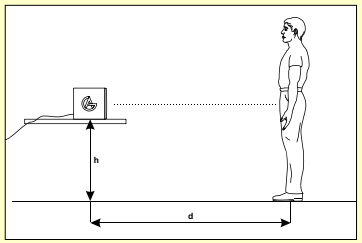
Renal cancer accounts for about 2-3% of all cancers.
In the last years an increasing incidence of renal cancer has been widely reported primarily as a result of an extensive use of imaging, especially ultrasound.

Presently in literature incidentally diagnosed renal cancer accounts for 25-40%, leading in most countries to a significant reduction of stage at diagnosis and as a consequence to a decline of cancer-specific mortality.
On this basis, a new diagnostic non invasive tool, TRIMprob™, has been considered for the screening of incidental renal cancer in order to evaluate its diagnostic reliability.

Here, we present a feasibility study designed to assess its diagnostic accuracy in in a small series affected by renal cancer and, thus, the utility to perform a wider study in this specific subset.



TRIMprob is based on a patent by PhD Clarbruno Vedruccio

Materials and Methods

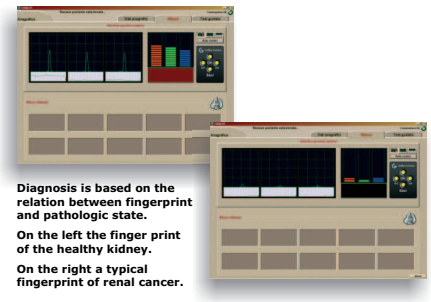
24 patients were evaluated with the TRIMprob™ device in the period between May 2003 and September 2003, in three different Italian hospitals. It has recently been proposed that cancer may behave differently to healthy tissue, when exposed to a low level electromagnetic incident wave.
An electromagnetic generator (TRIMprob™) has been used to produce an extremely low energy multiple frequency electromagnetic field, which can be used to test this theory.

The TRIMprob™ was moved over the surface of the patient's back while standing, bare-chested, in front of the system receiver, with the operator in the opposite side with respect to the kidney under test.
During the diagnostic test the incident beam must be oriented toward the kidney's area.

When the incident beam, during its propagations within the body, encounters a tissue in a diseased state, the electromagnetic field interacts with the tissue components at molecular level, and, by means of a resonant mechanism of power conversion here it is focused.
In this way, a new radio frequency signal is formed by the interference between the incident field and the scattered field from the tissues.

The sudden signal variation in negative sense, corresponding to a sudden attenuation of one or more spectral lines, constitutes the basis for diagnosing radiated tissues and structures.

A single operator, blinded to the patient status conducted the tests.
Three spectral lines were analysed at 465, 930 and 1395 MHz.



Diagnosis is based on the relation between fingerprint and pathologic state.

On the left the finger print of the healthy kidney.

On the right a typical fingerprint of renal cancer.

When a radiating source is located near a material body, the macroscopic average fields at all inside and outside points, depend on the electrical properties of the body, on its size, shape and its proximity to other objects.
External measurements of the field, at suitably chosen points, can be used to deduce the electrical properties of the material forming the body, and to reveal aspects of its structure. Such observation may involve the field components scattered from the body or transmitted into or through it.
If the interaction is sufficiently weak to produce only temporary condition of equilibrium in the microscopic structure, a modified average steady state electromagnetic field, both inside and outside the body, is observable, and it is from these measurements that the relevant macroscopic electrical properties of the material medium can be inferred.

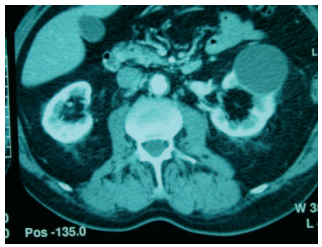
Results

48 renal units were tested with the TRIMprob™ device, 24 with renal cancer and 24 healthy kidneys. In 20 cases over 24 the device has correctly localized the patient's disease in the corresponding area.

A sensitivity of 83% and a specificity of 67 % have been calculated, with an accuracy of 75%, a positive predictive value of 71%, and a negative of 80%. 3 false negatives over 4 seem to be correlated with the dimensions of the pathology: in these cases the diameter of renal mass exceeded 6 cm.

DIAGNOSTIC PARAMETERS ON CANCER DETECTION	
SENSITIVITY	95%
SPECIFICITY	67%
ACCURACY	80%
POSITIVE PREDICTIVE VALUE	70%
NEGATIVE PREDICTIVE VALUE	94%

Calculating again the parameters excluding the patients with renal masses larger than 6 cm, a sensitivity of 95%, a specificity of 67%, an accuracy of 80%, a positive predictive value of 70% and a negative of 94% have been obtained.
It is worth noting that 3 false positives over 8 seem to be correlated to the presence of associated morbidities, such as kidney stones, abdominal aortic aneurism and abdominal lymphadenomegaly (response to be investigated).



TRIMprob false positive in patient with a paracaval lymphadenomegaly

Conclusions

The interesting and promising result of this study seems to provide an experimental evidence on the possibility to diagnose renal cancer by means of electromagnetic fields.
Since the required intensities of the electromagnetic waves are very low (the power is similar to a mobiles phone), it is really safe and non invasive. These initial results let us say that the detection is very simple and sensitive, and to suppose that the accuracy of the test is correlated in inverse proportion to the dimension of the lesion.
The collected data lead us to undertake a study devoted, by extending the number of patients enrolled, to establish and to optimize the performances of the approach.