Author's response to reviews

Title: Diagnosis of rectal cancer by Tissue Resonance Interaction Method

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Author's response to reviews: see over
December 10, 2009

Melissa Norton, MD
Editor-in-Chief
BMC Gastroenterology

Re: MS: 1316830238297738
Diagnosis of rectal cancer by electromagnetic device

Dear Dr. Norton,

Following the revision of our manuscript by BMC Medicine (email of October 16, 2009) and the suggestion to submit it to BMC Gastroenterology, we wish to thank you for your willingness to evaluate a revised version of our manuscript entitled “Diagnosis of rectal cancer by electromagnetic device”.

Enclosed please find a point-by-point explanation of the modifications in response to the reviewers’ comments (below) and the revised manuscript.

Sincerely,

Dott. Alberto Vannelli
Reviewer #1 - Cosimo De Nunzio

1- As requested, in the revised manuscript we have included ROC analysis and data on sensitivity, specificity, negative or positive predictive values, or accuracy (p. 4, lines 28-29; p. 5, lines 25-31; revised Fig. 2A). To evaluate the best cutoff values, we have also plotted the accuracy of the method by cutoff values (see revised Fig. 2B).

2- Although we have not strictly followed the flow diagram and check list of STARD initiative, we think that we have accurately reported all study details, according to the aims of the STARD initiative.

3- We have reported the comparison of data from TRIMprobe with those from colonoscopy (see Table 2).

4- We have assessed by computed tomography, as previously stated, that patients with a positive TRIMprobe did not present a bladder or prostate cancer. (p. 5, lines 8-11).

5- As requested, we have replaced Figure 2 by a Figure reporting data on diagnostic accuracy (ROC curve analysis) (see the revised Fig. 2).

6- We have added a sentence on the limitations of our study (p. 8, lines 17-23).

Reviewer #2 - Oner Sanli

1- As pointed out and agreed in our correspondence with Dr. Mick Aulakh (email of October 27, 2009), the specific request to analyze normal subjects cannot be addressed, since such request contrasts with the recruitment criteria (INT-D176767, ClinicalTrials.gov Protocol Record). Anyway, as requested, we have reported in the Discussion a sentence on the limitations of the study (p. 8, lines 17-23).

2- No prostate or other primary cancers were detected, using computed tomography and abdominal sonography (p. 5, lines 8-11).

3- In the limitations of the study we have also mentioned the low power, as requested (p. 8, lines 17-19).

4- We have not detected intraobserver and interobserver variability.

5- As we have previously stated in the Results, we found a significant inverse correlation between the size of the tumors and the value of the electromagnetic signal (p. 6, lines 9-11).

6- Our study was aimed exclusively to test the performance of TRIMprobe in rectal cancer.

7- As requested, we have shortened the Discussion.

8- We have briefly mentioned the results of this technology on other cancers with favorable outcomes (p. 7, lines 30-31; Refs. 16-17).

9- We have briefly discussed about limitations of the technique due to operator dependence and effect of other GIS diseases (p. 8, lines 17-23).

Minor essential revisions:

1- We have deleted the part of sentence, as requested (p. 3, line 10).
2. “Please correct me I may be wrong; but when I calculate patients with negative (196 pts) and positive biopsy (208 pts, both rectal and upper GIS) it makes 405 not 415.” Both the 405 and 415 numbers are correct, since 10 patients refused the protocol, as stated (p. 3, lines 27-28).