



DERMOSCOPY AND SKIN IMAGING

TWO ARMS RANDOMIZED CLINICAL TRIAL COMPARING THE PERFORMANCE OF DERMOSCOPY AND IN-VIVO CONFOCAL MICROSCOPY VERSUS DERMOSCOPY ALONE FOR THE DIAGNOSIS OF SKIN TUMORS IN A 3 HOSPITALS NETWORK (NET-2011).

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Background: In-vivo reflectance confocal microscopy (RCM), a second level non-invasive imaging technique, has been proven to be a useful tool for skin tumors diagnosis, allowing to reduce unnecessary excisions of benign lesions, while catching malignant skin tumors. However, the diagnostic performance of RCM was almost exclusively assessed in observational studies.

Objective: Our aim was to prospectively evaluate in a clinical trial the performance of RCM as a second level examination, as compared to clinical and dermoscopic examinations alone.

Materials and Methods: A prospective multicentric randomized trial was conducted. Patients with at least one skin lesion suspicious for melanoma were consecutively enrolled in 3 Italian centers (Modena, Reggio Emilia and Ravenna). Lesions were randomly assigned to be examined with dermoscopy + RCM (arm1) or dermoscopy alone (arm0). In the first case the final decision was taken considering the combined clinical/dermoscopic/confocal findings; however, in arm0 lesions were always excised.

Results: A total of 1435 lesions were enrolled at the time of this 8-month preliminary analysis, of which 689 (48.0%) were randomly assigned to arm0 and 746 (52.0%) to arm1. In arm1, only 296 (39.7%) lesions were excised, while the remaining 450 (31.4%) were scheduled for follow up. Thus, 985/1435 lesions were immediately scheduled for excision, of which histopathological reports were available for 717 (arm0:496; arm1:221). In particular, 446 (62.2%) lesions were diagnosed as benign [arm0:327 (298 nevi); arm1:119





(111 nevi)] and 271 (37.8%) as malignant [arm0:169 (141 melanomas); arm1:102 (97 melanomas)]. We found that RCM allowed to save unnecessary excision of 449/568 benign lesions (79.0%); while, only one false negative melanoma was excised at follow up. We calculated 99.0% sensitivity and 79.0% specificity levels for the combination of clinical/dermoscopic/confocal examination.

Conclusions: RCM showed to significantly reduce the number of unnecessary excisions in a prospective clinical setting, with high specificity and sensitivity levels.

