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Research article

A new "hub and spoke" teledermoscopy system involving general practitioners and dermatologists for the early detection of cutaneous melanoma: a pilot study

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Abstract: The incidence of cutaneous melanoma has been increasing over the past few decades. The introduction of dermoscopy has enriched the diagnostic armamentarium of dermatologists improving diagnostic accuracy. The involvement of General Practitioners (GPs) and the use of telemedicine systems could constitute a new resource to make available early diagnosis to a larger population and to rationalize health resources in favor of patients at high risk of developing skin tumors. *Aims:* Primary aim of this study is to assess the feasibility of a "hub and spoke" model for the cooperation between high-specialty hospital units and GPs, using a new online teledermatology platform (I3DermoscopyApp®), that recently has been proved as a valid semiautomatic diagnostic image-based measurement system. Secondary aim is to evaluate the reliability of this semiautomatic diagnostic system in a clinical model of real life. *Methods:* An observational cross-sectional study using a "hub and spoke" model, was conducted at Dermatology Unit of Department of Clinical Medicine and Surgery of University Federico II of Naples. GPs and dermatologists were involved in this study after a demormoscopy traninig. *Results:* The system proved to be reliable in the triage phase and useful in the rationalization of highly specialized medical resources. Comparing patients diagnosed with malignant skin tumors through teledermoscopy system with patients with the same skin lesions of our department not participating to the study, we noticed that latency time between diagnosis and surgical excision were significantly decreased demonstrating the reliability of this semiautomatic diagnostic system in a clinical model of real life. *Discussion:* This study demonstrating the feasibility of a hub and spoke system based on a teledermatology cooperation between GPs and dermoscopy trained dermatologists. The use of teledermoscopy improves the ability of GPs selecting lesions suggestive of skin cancer without increasing the number of unnecessary expert consultations.

Keywords: teledermoscopy; melanoma; General Practitioners; early detection

1. Introduction

The incidence of cutaneous melanoma (CM) has been increasing steadily over the past few decades in Europe and throughout the world [1]. It is one of the most common malignant cancer occurring in young adults and represents a significant health concern, particularly in terms of years of life lost. A key prognostic factor of CM is the depth of the lesion in millimeters at the time of diagnosis. Melanoma in situ, which is confined to the epidermis, is considered completely curable. Thin melanoma (≤1mm) has a 5 year survival rate of 94%. However, once melanoma has progressed and metastasized, effective treatments are limited. The 5-year survival rate for patients with stage IV melanoma is less than 15% [2]. At this stage, CM responds poorly to radiation therapy and to treatment with chemotherapic drugs so, early diagnosis is mandatory. Several diagnostic tools have been developed to improve clinician's diagnostic accuracy. Among these, dermoscopy is one of the most used. Dermoscopy has enriched the diagnostic armamentarium of dermatologists with new morphological clues that are particularly useful to improve diagnostic accuracy of CM. However, the reported sensitivity and specificity of dermoscopy vary significantly between published studies, depending on dermatologists' experience and specific training [3]. The involvement of General Practitioners (GPs) and the simultaneous use of telemedicine systems could constitute a new resource to make available early diagnosis to a larger population and to rationalize health resources in favor of patients at high risk of developing skin tumors. In this study, we propose the activation of a "hub and spoke" model for the cooperation between high-specialty hospital units and GPs.

1.1. Aims

The primary aim of this study is to assess the feasibility of this model. Secondary aim is to evaluate the reliability of a semiautomatic diagnostic image-based measurement system (I3DermoscopyApp®) in a clinical model of real life.

2. Materials and methods

2.1. Ethics approval of research

The study was approved by local ethic committee (Ethic Committee University Federico II of Naples-Number of protocol: 140/17). A written informed consent was obtained from the patients for the publication of this study and accompanying images. The authors have no ethical conflicts to disclose.

2.2. *Clinical trial*

An observational cross-sectional study on "hub and spoke" model using a new teledermoscopy system, was conducted to make an early diagnosis of atypical pigmented skin lesions, in particular in high-risk patients (sun exposure history, >50 naevi, familiarity for melanoma or other skin cancers, phototype I/II), at Dermatology Unit of Department of Clinical Medicine and Surgery of University Federico II of Naples. The recruitment of patients run from March to June 2017 while follow-up and data collection period was of 24 months. Written informed consent was given. General Practitioners (GPs), voluntarily enrolled, and dermatologists were involved in this study after a dermoscopy training of 6 months. The study was approved by local ethic committee (Ethic Committee University Federico II of Naples-Number of protocol: 140/17) and according to the declaration of Helsinki. All GPs received a diagnostic device, Molescope® (by MetaOptima), a mobile dermatoscope, that captures a high-resolution, detailed view of skin lesions. The images of the lesions were sent by GPs through a web platform that archived them. The stored images were then analyzed using a software able to make a preliminary automatic diagnosis and, subsequently, they were analyzed by the expert dermatologists who made a further diagnosis. Histological examination of excided lesions is generally considered as the gold standard for diagnosis. However, due to ethical implication, it was impossible to excide even the lesions classified as “mild atypia”, so expert dermatologist opinion was considered as gold standard in this study. The platform utilized was I3D-dermoscopy (Internet Imaging Innovation-Dermoscopy) a dermatologist support app for the analysis of skin lesions based on the detection of 7-Point Check List dermoscopic criteria, using an automatic processing of dermoscopic images. All melanocytic lesions were included in the study, whereas, non-melanocytic lesions were excluded because of their specific dermoscopic features not compatible 7-point checklist. For each enrolled patients information about sex, age, number of naevi, familiarity for melanoma or other skin cancers, phototype and anatomical site has been collected by GPs. For each patient in the platform two images and patient information were uploaded after performed a complete skin evaluation. The images taken were analyzed by both the platform and the expert dermatologist according to the grade of atypia. Four levels were considered: absente, low, moderate and severe atypia. The platform selected the grades of atypia according to the 7-Point Check List as shown in Figure 1, whereas the expert dermatologists re-evaluated the global clinical and dermoscopic images compared to the personal data of each patient that were reported in the form filled by GPs.

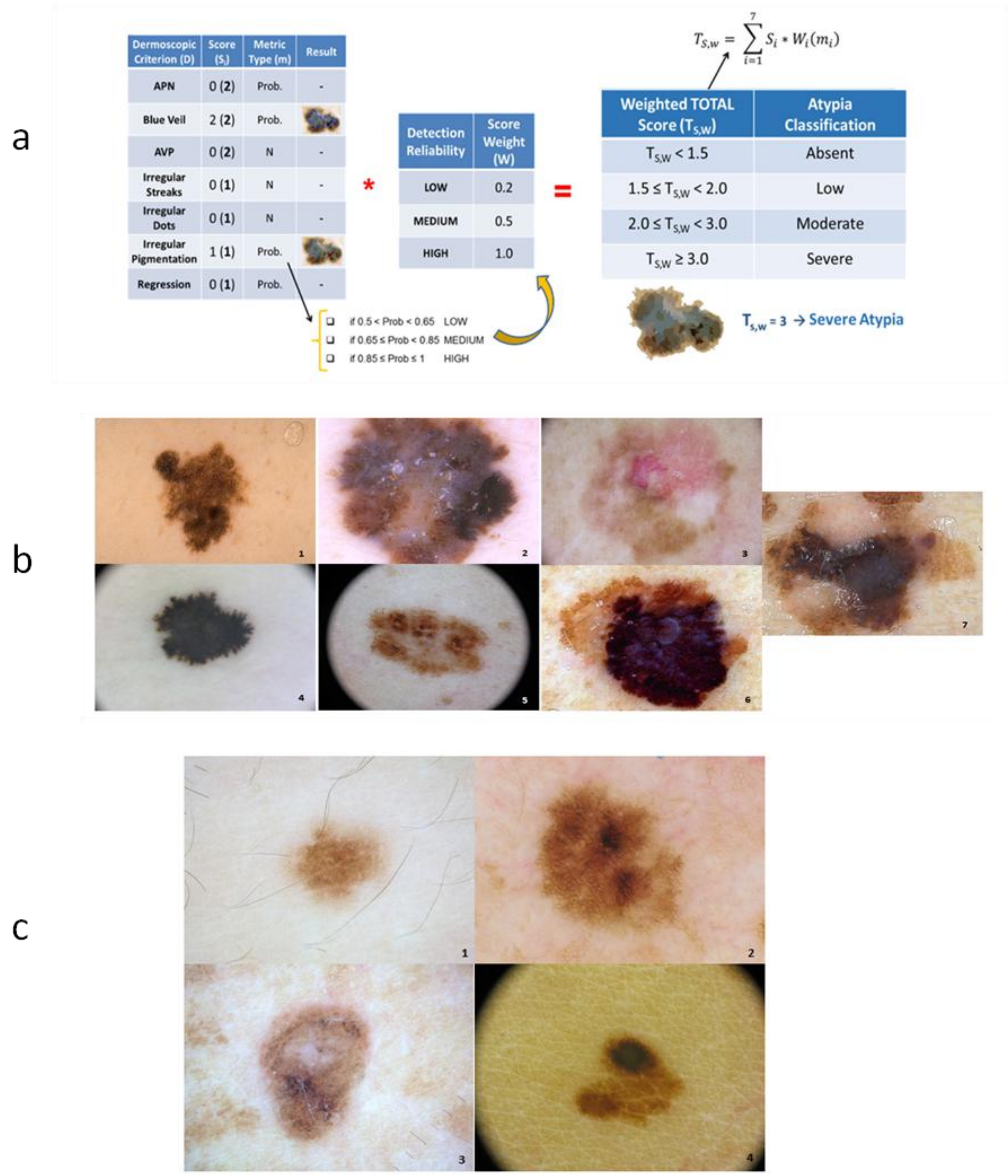


Figure 1. (a) Scheme of the automatic analysis of dermoscopic image provided by the I3d platform; (b) Detail of all dermoscopic criterion of 7 point checklist (1. APN; 2. Blue Veil; 3.AVP; 4. Irregular Streaks; 5. Irregualr Dots; 6. Irregular Pigmentation; 7. Regression); (c) Images for 1. Absence of atypia, 2. Mild atypia, 3. Moderate atypia and 4. Strong atypia assessed by I3D platform.

In detail, the platform deploys the most outstanding literature results as well as the authors' proposal about the adoption of feature extraction techniques, classification methods and statistical analysis of suspicious skin lesions. Thus, the main biological structures (corresponding to the dermoscopic criteria included in the 7-Point Checklist) are highlighted by applying to each lesion the image processing techniques briefly reported in Table 1.

Table 1. Image processing techniques.

ELM criterion	Atypical pigment network	Blue-whitish veil	Atypical vascular pattern	Irregular streaks	Regression structures	Irregular pigmentation	Irregular dots/globules
Score	2	2	2	1	1	1	1
Definition	Prominent (hyperpigmented and broad) and irregular network	Irregular, confluent, gray-blue to whitish blue pigmentation not associated with red-blue lacunes or maple leaf pigmentation	Linear, dotted or globular red structures irregularly distributed outside areas of regression	Radially and asymmetrically arranged linear or extensions at the edge of the lesion	White and gray-blue areas, peppering, multiple blue-gray dots associated	Brown, gray and black areas of diffuse pigmentation with irregular shape or disruption and abrupt end	Black, brown or blue round structures irregularly distributed within the lesion
Histological Correlates	Hyperpigmented or broadened ridges with irregular shape or distribution	Pigmented melanophages or melanocytes of midreticular dermis location	Neovacularization or vascularized nets of amelanocitic cells	Confluent radial junctional nests of melanocytes.	Areas of loss of pigmentation and fibroplasias, with scattered melanophages	Hyperpigmentation throughout all levels of epidermis or upper dermis	Aggregates of pigment of stratum corneum, junctional or dermis location
Main features	Texture	Color	Structures/Color	Structures	Color	Color	Structures
Feature Extraction	Structural Analysis	Principal Component Analysis 2D Thresholding	SRM Structural Analysis	Structural Analysis SRM	SRM	SRM	SRM Structural Analysis

As further step, a statistical analysis is performed with the aim of providing the measurement information about the reliability of the adopted procedure for each criterion detection. Thus, a label (Low, Medium or High) is assigned to each dermoscopic structure detected according to different ranges for the corresponding metric value, which is introduced for qualifying the processing algorithm.

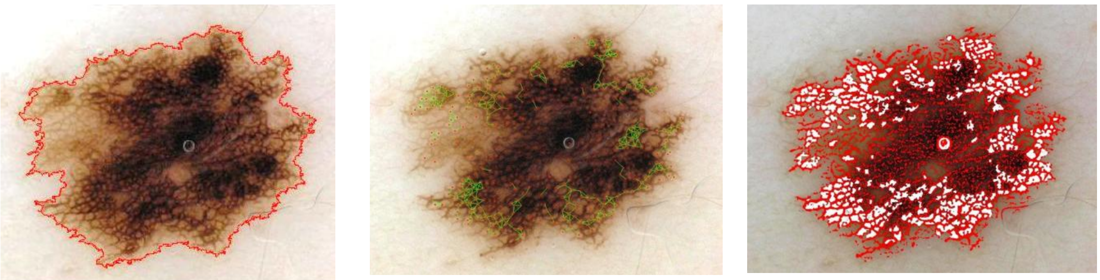
As an example, the chromatically homogeneous regions (low-level structures) resulting from the segmentation performed through the Statistical Region Merging (SRM) are classified by means of a suitable Logistic Model Tree (LMT). The Irregular Pigmentation is detected when (at least) one segment of the lesion map is classified as irregular; then, the reliability of the automatic detection is evaluated by considering the probability $P_{1,Sirr}$ (computed by the LMT for the widest irregular segment *Sirr*) according to the following ranges:

Low if $0.5 < P_{1,Sirr} < 0.65$

Medium if $0.65 \leq P_{1,Sirr} < 0.85$

High if $0.85 \leq P_{1,Sirr} \leq 1$

Another classification is based on the texture of the dermoscopic image, with an x vector of 69 structural, geometric and chromatic characteristics being extracted to describe the structure of the lesion of interest by adopting the graph-based approach (introduced in Sadeghi et al. [4]) and the iterative cycle counting algorithm suggested in Kirk [5]. As an example, Figure 2 highlights the darker mesh of the pigmented network (the *"net"*) and the lighter colored areas (the *"holes"*) surrounded by the net.



a) b) c)

Figure 2. Detection of Atypical Pigmented Network: (a) lesion and superimposed contour; (b) result of the Graph-based approach; (c) highlight of the Atypical Pigmented Network (with High probability).

The automatic detection of the dermoscopic criterion appears as a three-class problem (Absent/Typical/Atypical Classification). Again, the Logistic Model Tree approach is adopted as solution to compute the probabilities P_i for the pigmented network according to the generalization corresponding respectively to the Atypical, Typical and Absent classes.

The Atypical Pigmented Network is detected if

$\arg_i \max P_i = 1$

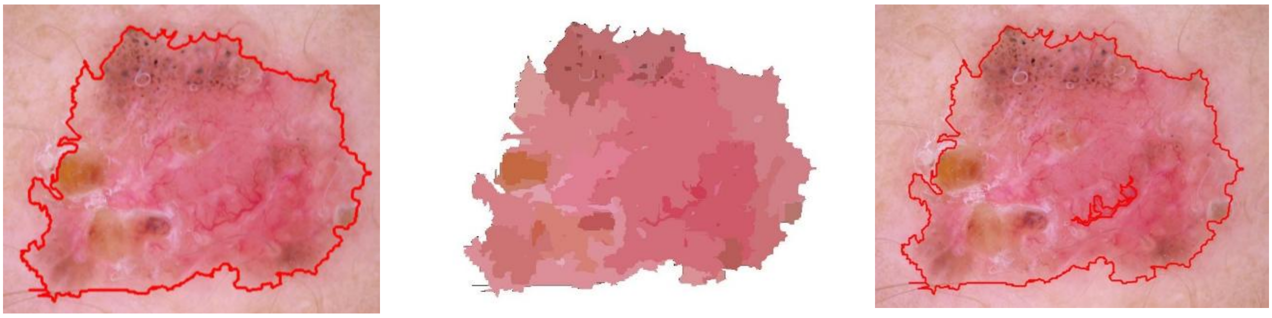
whereas, the detection reliability is estimated by considering the following labels:

Low if $0.34 < P_i < 0.65$

Medium if $0.65 \leq P_i < 0.85$

High if $0.85 \leq P_i \leq 1$

In order to detect vascular patterns, automatic detection of the dermoscopic criterion is adopted, integrates structural analysis and chromatic measurement of the lesion: the main linear/globular structures are selected through the image, improving the response of the tubularness filter [6] and combined with the red segments resulting from the application of the merger of the statistical region at the fine level (Q = 256) in the internal area (see Figure 3).



a) b) c)

Figure 3. (a) ELM image and lesion contour; (b) SRM segmentation of the lesion area; (c) automatic detection of AVP.

Then, the spatial distribution of the candidate low-level characteristics with respect to the main axes of lesion symmetry is evaluated. In fact, the binomial distribution is expected when the red linear/globular structures are randomly scattered in each of the 4 quadrants (resulting from the design of the major and minor axis of the ellipse characterized by the same second normalized central moments of the lesion). Therefore, the analysis of the atypical vascular model is performed by performing a binomial test on the linear/globular objects highlighted with N. If the scarcity or abundance (with respect to the expected value) of the low characteristics is measured in any quadrant and/or pair of quadrants level, the null hypothesis (i.e. the random distribution of N linear/globular objects) can be rejected with the accepted risk α of type I error and the atypical vascular model is detected.

Moreover, the reliability of the classification procedure can be labelled according to the following scheme:

Low if $N < 15$
Medium if $15 \leq N < 30$
High if $N \geq 30$

Automatic detection of small dark areas within the lesion is provided through the analysis of the chromatic and morphological measurement about the segments highlighted, as previously introduced, by the Statistical Region Merging at fine level. In detail, the chromatically uniform regions (low-level features) are ordered according to the (increasing) value of Intensity value, within a suitable range for Hue component. Then, based on the experimental testing and tuning activity, thresholding operation is performed with respect to the morphological feature descriptors represented by the region percentage area $A_{\%}$ and eccentricity e, in order to select N significant rounded objects inside the lesion. Again, the casual (spatial) distribution of the observed items is analyzed with respect to the main symmetry axes of the lesion. If the number of the dark round objects in each quadrant is out of the expected range from the Binomial Distribution, the Null Hypothesis of uniform distribution is refused, and the corresponding low-level features are classified as Irregular Dots and Globules.

The reliability of the automatic detection is estimated as follows:

Low if $N < 20$
Medium if $20 \leq N < 50$
High if $N \geq 50$

Two approaches, both based on the adoption of color segmentation and structural analysis, are provided for the automatic detection of linear or bulbous extensions asymmetrically arranged at the edge of the lesion.

The former approach (depicted in Figure 4) is able to: a) detect the black/brown pigmentation localized along the lesion periphery; and b) track the finger-like contour of the highlighted structure (which is split into 10 equal-length segments). Finally, a morphological irregularity index is determined as ratio of number of pixels constituting the lesion contour and the shortest path and compared with a suitable threshold (experimentally estimated during the training phase) to determine the set S_{IRR} of candidate segments with streaks.

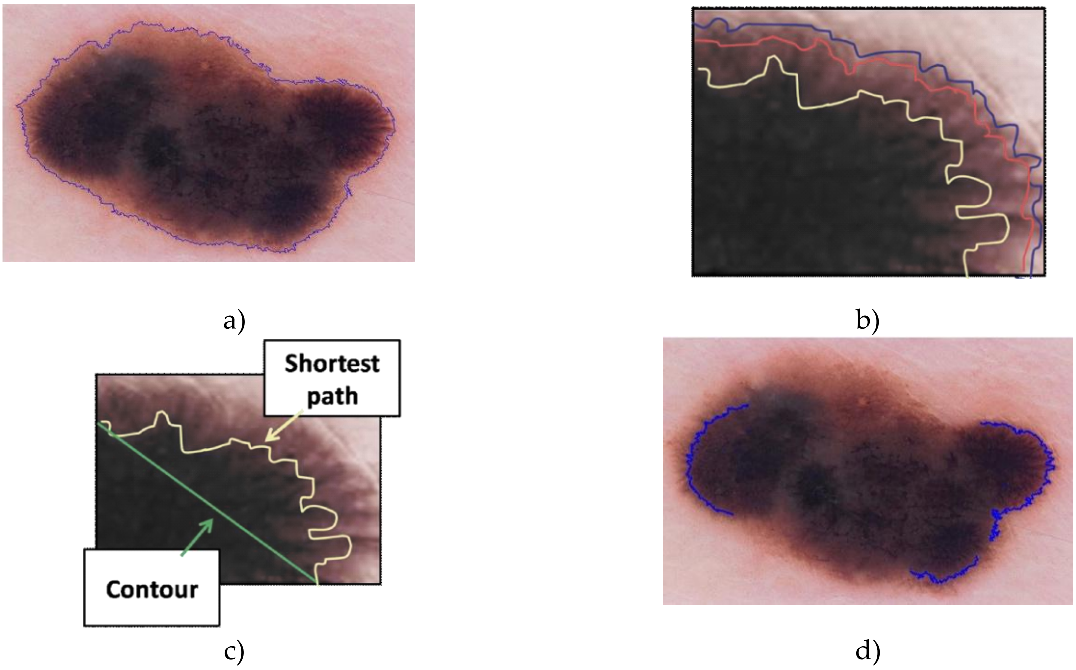


Figure 4. Detection of Irregular Streaks: (a) ELM image and lesion contour; (b) the lesion area next to the border segment (blue line) is investigated (color segmentation based on SRM) searching for darkest regions; (c) finger-like structures are detected through.

According to the latter approach, the flux analysis of the streaks' principle curvature vectors [7] is performed by adopting the Frangi Filter[6]. In detail, the parallel and perpendicular flow for the streak vector field are measured over the equal-length segments of the lesion border. The candidate segments with streaks are included in S_{FRANGI} set by comparing the corresponding mean values and variances of the measured flows with experimentally tuned thresholds.

The presence of Irregular Streaks and the reliability of the corresponding procedure are provided by combining the introduced approaches according to the following scheme:

Low if $0 = \dim(S_{FRANGI}) < \dim(S_{IRR}) = 1$

Medium if $\dim(S_{FRANGI} \cap S_{IRR}) = 1$

High if $\dim(S_{FRANGI} \cap S_{IRR}) > 1$

A weighted version of 7-Point Check List scoring system is suggested for the automatic lesion classification, which takes into account all the detection algorithms and the corresponding reliability. In detail, 3 constants have been associated experimentally to the reliability of the detection procedures (0.2, 0.5 and 1.0, corresponding to the LOW, MEDIUM and HIGH labels respectively) and are adopted to weight the partial scores according to the detection uncertainty. Finally, the total score for the skin lesion is achieved by summing-up the seven weighted scores, and the automatic classification of the corresponding atypia is provided.

During teleconsultation dermatologists planned live medical visits for all patients with a priority proportionate to the characteristics of analyzed lesions with a specific triage: lesions with absence of atypia were evaluated after three months; lesions with low atypia were evaluated after two months, lesions with moderate atypia were evaluated in one month and lesions that presented a severe grade of atypia were evaluated in 7–15 days.

At the follow-up clinic visit the expert dermatologists made a total body clinical and dermoscopic exam of each patient, comparing the images previously selected and sent on online platform by the GPs to face to face examined images confirming or not the diagnosis. The diagnosis made from expert dermatologists during live visit (eventually supported from histological examination in case of excision) was considered the gold standard for diagnosis.

Finally, to evaluate the utility of our model in the optimization and speeding up early diagnosis of skin melanocitic tumors, we compared the time from diagnosis to excision between patients with malignant pigmented skin tumors detected by teledermoscopy system, and patients, with the same skin lesions, attending outpatient of Dermatology Unit of Department of Clinical Medicine and Surgery of University Federico II of Naples.

2.3. Statistical analysis

The continuous variables were described using mean and standard deviation (SD), while the categorical variables were described using frequency and percentages. Reproducibility of I3d automatic opinion and expert opinion was evaluated by measuring the weighted Cohen Kappa (k) coefficient. The 95% confidence interval (CI) of k value was calculated. Definite atypia according to the gold standard evaluation was used to evaluate accuracy of the tests. Specifically, accuracy of I3d automatic opinion and expert opinion was evaluated by Receiver Operating Characteristic (ROC) curves. ROC curve depicts the relation between true positive (sensitivity) and false positive (1-specificity) for each scoring system [8]. The corresponding ROC curves were plotted and area under the curve (AUC) calculated according to the trapezoid method [8]. A value of AUC = 0.5 indicates that the score performs no better than chance and a value of AUC = 1.0 indicates perfect discrimination. AUC values were compared with the DeLong method [9]. For each score, sensitivity, specificity and Youden index (i.e. sensitivity + specificity-1) were calculated for different values of the score. The best Youden index also determines the best cut-off point [10]. At best cut-off point sensitivity, specificity, negative predictive value (NPV) and positive predictive value (PPV) with calculated with 95% exact confidence intervals were estimated. *p*-value less than 0.05 was accepted as statistically significant. Data were analyzed using SAS version 9.4 (SAS Inc, Cary, NC, USA) and R software version 3.3.1 (R Foundation for Statistical Computing, Vienna, Austria).

3. Results

The system proved to be a useful tool for the cooperation between high-specialty hospital units and GPs.

Overall 68 General Practitioners (GPs) and 28 dermatologists participated to this study. In total 131 patients were enrolled and 327 dermoscopic images were captured and sent by on line platform. Of this, 104 (79%) patients participated to follow-up face to face visit with 116 sites evaluated.

Patients and site characteristics are reported in Table 2.

Table 2. Characteristics of patients and site.

	N	(%)
Gender, (n = 104)		
Female	69	(66.4)
Male	35	(33.7)
Age year, (n = 104) mean ± SD	46.5 ± 19.5	
Site, (n = 117)		
missing	1	(0.9)
abdomen	3	(2.6)
lowerlimbs	17	(14.5)
upperlimbs	5	(4.3)
axilla	1	(0.9)
right arm	1	(0.9)
head	2	(1.7)
neck	3	(2.6)
back	46	(39.3)
right side	2	(1.7)
groin	1	(0.9)
hand	1	(0.9)
sole	1	(0.9)
breast	1	(0.9)
sternum	1	(0.9)
temple	1	(0.9)
trunk	27	(23.1)
face	3	(2.6)

The mean age was 46.5 years and 69 patients were female (66.4%). Among the uploaded images sites back, trunk and lower limb were more frequent (39.3%, 23.1% and 14.5% respectively).

Comparing patients with the same human factors diagnosed with malignant skin tumors through teledermoscopy system with patients with the same skin lesions of our Department not participating to the study, we noticed that latency time between diagnosis and surgical excision were significantly decreased. In particular, with teledermatology approach there was an average waiting time of 10.7 days respect to 47.6 days of waiting list necessary for patients attending our Dermatology Unit.

Distribution of I3d automatic opinion and expert opinion are reported in Table 3. 52 out of 116 (44.8%) sites had the same diagnosis for both automatic and expert opinion.

Table 3. Distribution of lesions by I3d automatic opinion and expert opinion.

	Expert opinion				
i3d automatic opinion	Absence of atypia	Mild atypia	Moderate atypia	Strong atypia	Total (%)
Absence of atypia	40	12	6	2	60 (51.7)
Mild atypia	11	8	1	0	20 (17.2)
Moderate atypia	7	2	1	0	10 (8.6)
Strong atypia	13	5	5	3	26(22.4)
Total (%)	71 (61.2)	27 (23.1)	13 (11.2)	5 (4.3)	116 (100.0)

A poor agreement was observed between I3d automatic opinion and expert opinion with a weighted Kappa value of 0.133 (95% CI-0.006 to 0.272). Out of 116 lesions evaluated 13 (11.2%) had a definite atypia according to the gold standard evaluation. ROC curves for the two scoring systems were reported in Figure 5.

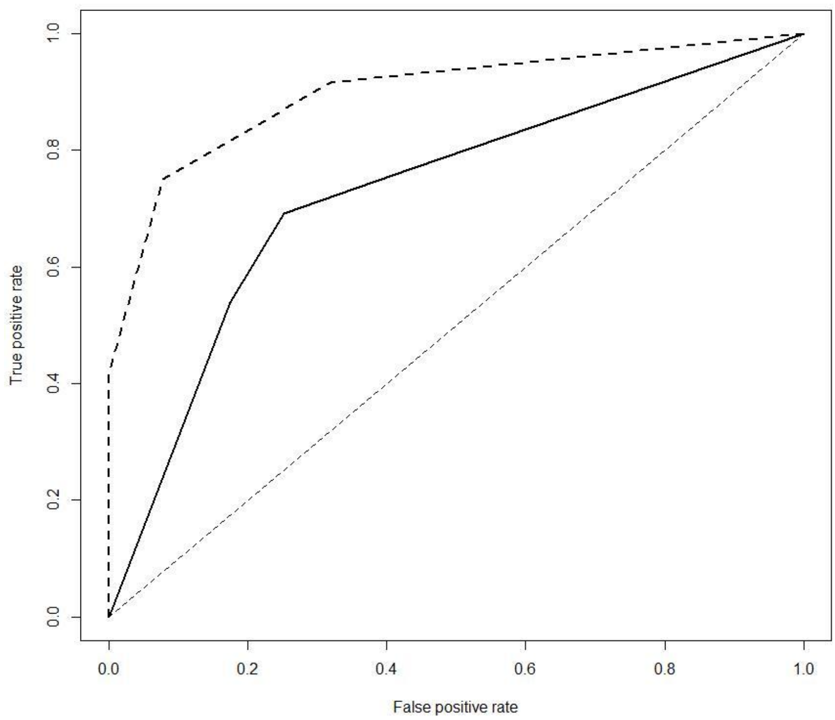


Figure 5. ROC curves for I3d automatic opinion (solid line) and expert opinion (dotted line).

No significant difference (p-value = 0.160) was found in the comparison of AUC value of I3d automatic opinion 0.728 (95%CI0.577 to 0.879) and expert opinion 0.899 (95%CI0.789 to 1.000). For I3d automatic opinion the best cut-off point was to classify moderate-strong vs. mild-absence with a sensitivity of 69.2% (95%CI38.6%–90.9%), specificity of 74.8% (95%CI65.2%–82.8%), PPV of 25.7% (95%CI12.5%–43.3%) and NPV of 95.1% (95%CI87.8%–98.6%). For expert opinion the best cut-off point was to classify moderate-strong vs mild-absence with a sensitivity of 69.2% (95%CI38.6%–90.9%), specificity of 92.2% (95%CI85.3%–96.6%), PPV of 52.9% (95%CI27.8%–77.0%) and NPV of 96.0% (95%CI90.0%–98.9%). Moreover, after clinic and dermoscopic evaluation, a total of 36 lesions were excised, 18 of which defined as moderate/strong atypia by the expert opinion, 18 identified by the expert during clinical and dermoscopic live evaluation and escaped the attention of GPs. Histologycal examination resulted as follow: 10 melanoma (6 superficial spreading melanoma and 4 thick melanoma), 26 atypical pigmented lesions (16 dysplastic nevi and 10 Spitz/Reed nevi). For each of this excised lesions we made a follow-up of 3 months and the survival rate was of 100% for 32 patients (6 of whom affected by superficial spreading melanoma, 16 by dysplastic nevi and 10 by Spitz/Reed nevi) and of 60% for patients affected by thick melanoma.

4. Discussion

Recently, teledermoscopy and its impact in clinical practice has been thoroughly studied and described. It represents a suitable technique in Dermatology, that relies mainly on visual diagnosis [11]. Teledermatology has a wide spectrum of advantages. Firstly, it supports prevention, encouraging patients' personal skin self-examination [12]. Moreover, it gives the possibility to have a fast interface with dermatologists on potentially malignant lesions also over great distances [13].

It also allows to rationalize access to highly specialized structures by assigning lesions a targeted triage and thus lightening waiting lists.

Currently, it is thought that a face to face approach should remain in case of suspicion of malignancy [14], but the integration of macroscopic pictures and the use of high quality dermoscopic images enable us to have a good clinical correlation [11]. However, critical aspects for the reliability of teledermoscopy are the expertise of the observer physician and the diagnostic complexity of difficult cutaneous lesions [15].

In our study, the collaboration between GPs and a group of dermoscopy trained dermatologists allowed to raise awareness on suspicious skin lesions, giving a quick connection with patients at risk. Teledermoscopy can be considered a high quality useful tool to shorten waiting lists for melanoma excision and to select cutaneous lesions at greater risk of malignancy. Another advantage emerging from our study was the rationalization of diagnostic resources: the face-to-face examination was optimized according to the estimated severity (e.g. suspected melanomas have were evaluated in 7–15 days) both reducing latency time between the first visit and the surgical excision while lengthening waiting times for lesions without atypia to teleconsultation.

The low specificity observed for the software, is in accordance with the literature data which identify the main limit of the automated systems in the tendency to an excess of false positives confirming, in our opinion, the impossibility of using any automated system such as totally autonomous and independent diagnostic tool from the judgment of a human evaluator. For sure, with a higher number of images, an improvement in the machine learning platform performance could be obtained.

This is a pilot study, so our data need to be integrated with a higher number of cases. We cannot exclude that not only GPs, but also dermatologists may benefit from the teledermoscopy service. In fact, dermatologists with a limited experience in dermoscopy can have an expert opinion and, in case of a prompt surgical intervention in a hospital setting, the specialists can discuss the case remotely.

5. Conclusion

In conclusion to our knowledge this study demonstrates the feasibility of a hub and spoke system based on a teledermatology cooperation between GPs and dermoscopy trained dermatologists. The use of teledermoscopy improves the ability of GPs to make dermoscopy examination available to a large number of patients, selecting lesions suggestive of skin cancer without increasing the number of unnecessary expert consultations. In addition, the platform tested only in experimental conditions until now, has proved useful in a real life context. The application of teledermatology approach in dermatology is useful especially for skin tumors because there is often an overload, in highly specialized structures, of waiting lists for unnecessary investigations for benign lesions at the expence of malignant ones. Limitation is the impossibility to compare the dermoscopic diagnoses with the histological ones. In fact, the removal of lesions diagnosed as benign by expert dermatologists is not ethically acceptable.

Due to the use of telemedicine we have been able to sensitize to screening also patients who would never have carried out a mole check. Anyway, due to small sample size further high-quality, prospective, investigations are needed to better characterize the feasibility of teledermoscopy programs among GPs.

Statement of ethics

A written informed consent was obtained from the patients for the publication of this study and accompanying images. The authors have no ethical conflicts to disclose.

Disclosure statement

The authors have no conflicts of interest to declare.

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Author contributions

Gabriella Fabbrocini conceived the work.

Massimiliano Scalvenzi approved the version to be published.

Paolo Chiodini, Matteo Ferro, Giuseppe Di Leo, Paolo Sommella wrote the manuscript and analysed data.

Sara Cacciapuoti wrote the manuscript and revised it critically.

Claudia Costa, Mariantonietta Luciano, Serena Poggi and wrote the manuscript and acquired data.

Silvestro Scotti and Luigi Sparano acquired data.

Gaia De Fata Salvatores drafted the work and ensured the accuracy of any part of it.

Conflict of interest

The authors declare no conflict of interest.

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