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Patient acceptance and trust in automated computer-assisted diagnosis of melanoma with dermatofluoroscopy

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Summary

Background and objectives: Automated computer-guided diagnostic procedures are increasingly being integrated into patient care. However, in contrast to the increasing application of automation, patient acceptance and trust in such technologies has rarely been studied. Automated diagnosis of melanoma with dermatofluoroscopy was recently approved by regulatory agencies. The objective of this study is to assess patient acceptance and trust in automated melanoma diagnosis with dermatofluoroscopy.

Patients and methods: We examined 140 pigmented skin lesions with dermatofluoroscopy as part of a prospective clinical study. Four weeks after their examination with dermatofluoroscopy, we contacted 100 patients with a 10-item questionnaire addressing their acceptance and trust in this technology on a five-point visual analogue scale.

Results: A "high" to "very high" level of patient acceptance and trust in dermatofluoroscopy was found in 74 % of responders. Most patients agreed that computer-assisted diagnoses are trustworthy and may generally improve the diagnostic performance of physicians. However, all responders insisted on the interpretation of computer-assisted diagnoses by a physician and frequently rejected the idea of computers completely replacing physicians.

Conclusion: Patient acceptance and trust in dermatofluoroscopy was high. Patients clearly supported the use of automated, computer-assisted diagnostics as an adjunct to the physicians' examination.

Introduction

Automated computer-assisted diagnostic and therapeutic procedures are now an indispensable component of patient care and will be of increasing importance in the future [1]. However, there is a marked discrepancy between these developments and our existing knowledge of patient acceptance and trust in such innovative technologies. As a result, this may become a limiting factor for any larger scale application [2]. Understanding patients' trust in automated, computer-assisted medical technologies may provide some insight into potential changes in the patient-physician relationship, as the role of the physician moves from direct control to supervisory control [3]. Recently, several non-invasive diagnostic methods have been introduced to improve the accuracy of diagnosing melanoma [4]. Among these, dermatofluoroscopy (formerly described as "stepwise two-photon-laser spectroscopy"), is a tool that generates an automated diagnostic score and is intended for examination of a restricted number of preselected lesions with suspected melanoma [5]. In preclinical studies using freshly excised or paraffin-embedded tissue, dermatofluoroscopy showed high sensitivity and specificity

rates for the diagnosis of melanoma of 93.5 % and 80.0 % respectively [6, 7]. As an adjunct to an initial prospective, multicenter clinical study investigating the diagnostic accuracy of the "Magnosco DFC1" dermatofluoroscope (Magnosco GmbH, Deuben, Germany) in pigmented lesions suspected of melanoma (FLuorescence Identification of Melanoma by a Multicenter Based Algorithm [FLIMMA], ClinicalTrials.gov Identifier NCT02425475 [5]), we aimed at measuring patient acceptance and trust in this novel diagnostic technology with the help of a 10-item questionnaire, which also addressed open questions concerning potential changes in the patient-physician relationship.

Patients and methods

Study design and collection of data

This is a prospective, single-center, non-interventional evaluation of patients' acceptance and trust in dermatofluoroscopy, which is an automated, computer-assisted diagnostic device for the detection of cutaneous melanoma. The study was approved by the ethics committee of the medical faculty of the University of Heidelberg (approval no S-472/2016) and performed in accordance with the principles of the Declaration of Helsinki. Prior to the dermatofluoroscopy procedure, participants received extensive information on the technical background of the technology. Four weeks after the dermatofluoroscopy examination and excision of individual pigmented skin lesions (PSLs), study participants were contacted by mail and asked to provide their written informed consent and to fill in a 10-item questionnaire. The questionnaire was based on the validated "trust in medical technology" (TMT) instrument, which requires responders to have specific personal experience with the medical technology in question [8]. Participants were asked to indicate their level of agreement on a five-point visual analogue scale (1 = very high agreement; 2 = high agreement; 3 = moderate agreement; 4 = low agreement; 5 = no agreement) concerning ten different statements: S1: Examination with the dermatofluoroscopy device gave me a feeling of increased safety; S2: I consider the dermatofluoroscopy technology trustworthy; S3: I believe that a computer may improve the performance of a physician; S4: I would trust the results of computer-assisted diagnostics; S5: I believe that a computer may completely replace the examination by a physician; S6: I believe that computers may offer a higher diagnostic quality than physicians; S7: I would like the opinion of an expert physician in addition to the computer-assisted diagnosis; S8: I would accept longer examination times for an additional computer-assisted diagnosis; S9: I believe that technical devices should not be used in the context of healthcare; S10: In my everyday life I trust technical devices intended to increase my safety (e.g. optical smoke

detector, parking assistant). Moreover, undecided patients were given the option of indicating "Don't know". Additionally, the following patients' characteristics were systematically collected: gender, age, hair color, eye color, Fitzpatrick skin type, current degree of skin tanning, presence of ephelides (freckles), personal/family history of melanoma, number of common nevi, number of atypical nevi, number of lesions excised during the study, dermatofluoroscopy score, and histopathological diagnosis. All data were transferred into a Microsoft Excel database (Version 10, Microsoft Corp, Redmond, Washington, USA), de-identified, and used for statistical analysis.

Statistical analysis

In a first step, descriptive statistics were calculated for the patient characteristics. The mean and standard distribution were provided for continuous variables, and relative frequencies for categorical variables. We also compared the characteristics between melanoma and non-melanoma patients and applied t-tests or chi-squared tests to test for inequality between these patients. In a next step, the results of the questionnaire were analyzed descriptively and visualized using bar charts. To evaluate the predictive value of age, gender and the prevalence of a melanoma, univariate proportional odds logistic regression models were fitted separately for each variable and each question in the questionnaire.

Results

Baseline characteristics

From March 1st, 2015 to May 31st, 2016 we included 140 PSLs in 107 patients, which were assessed by dermatofluoroscopy followed by excision [5]. We managed to contact 100 patients by mail to complete the questionnaire. In the remaining seven patients, no valid mail address was known. Sixty-five patients (median age 62 years, range 23–88 years, 56.9 % male) returned fully completed questionnaires, resulting in a response rate of 65 %. Among the responders, 21 (32.3 %) were diagnosed with cutaneous melanoma during the study. We compared the characteristics of responders to the questionnaire and non-responders, and found a significantly different median age in responders (62 years) versus non-responders (48 years), p = 0.003. All remaining parameters showed no significant differences between the two groups. In particular, there was no significant difference in the distribution of gender or diagnosis of melanoma during the study. Overall, histopathology revealed 32 (22.8 %) melanomas in 140 excised PSLs. Analysis of differences between the characteristics and phenotypical traits of melanoma patients and non-melanoma patients revealed that melanoma

patients were significantly older (median age 66.5 years vs. 53 years; p < 0.001), had blue eyes more frequently (51.6 % vs. 21.9 %; p = 0.006), and had less melanocytic lesions requiring excision due to suspected melanoma during the study (mean number of excised lesions 1.1 versus 1.4, p = 0.006).

Analysis of the questionnaire

The questionnaire contained ten statements (S1–S10) based on the validated "trust in medical technology" instrument (TMT) [8], and the level of agreement of responders was measured with a five-step visual analogue scale (Figure 1). The first two statements (S1, S2) were specifically related to the use of the dermatofluoroscope during the preceding clinical study. Seventy-four percent of participants indicated a high or very high level of agreement for S1 and S2. None of the 65 participants completely rejected these statements and only one participant indicated low agreement. The next four statements (S3–S6) addressed patient acceptance and trust in computer-assisted diagnoses more generally. Most patients indicated at least high agreement that computer-assisted diagnoses may generally improve the diagnostic performance of physicians (78.5 %, S3) and are trustworthy (74 %, S4). In addition, many patients rejected (no agreement or low agreement) the idea of computers completely replacing physicians (60 %, S5) or of computers offering a higher diagnostic quality than physicians (54 %, S6). None of the participants indicated very high agreement for these statements. Still, a significant fraction of 35.4 % and 43 % of participants indicated moderate or high agreement to S5 and S6 respectively. This gives an idea of the potential trust in future developments of more autonomous systems in healthcare. The seventh statement tested the participants' attitude towards a potential change in the patient-physician relationship: all responders insisted on the additional opinion of an expert physician (100 % high or very high agreement). More than half of the respondents (55.4 %) would be willing to accept longer examination times for a computer-assisted diagnosis (S8), while 10.8 % rejected this statement. Statement S9 "I believe that technical devices should not be used in the context of healthcare" was rejected by 89.2 % of participants. S10 aimed at measuring the participants' general trust in technical devices in everyday life apart from applications in healthcare. This statement found a high level of agreement among responders (87.7 % high or very high agreement) (Figure 1).

Impact of patients' characteristics on the level of agreement

A proportional odds logistic regression model revealed that the participants' age significantly influenced the level of agreement on S1, S2, S4, S5, and S6, which were related to

the use of the dermatofluoroscope and more generally addressed patient acceptance and trust in computer-assisted diagnoses. Older age was associated with a significantly higher level of agreement for all these statements (all p < 0.015). Analysis of the impact of patients' gender on the level of agreement revealed a significantly higher level of agreement (p = 0.047) in male patients for S8. A non-significant trend for a higher level of agreement with all remaining statements of the questionnaire was noticed in male patients. No significant associations between the diagnosis of melanoma during the study and the level of agreement for the statements of the questionnaire were found with the proportional odds logistic regression model.

Discussion

In recent years, numerous computer-assisted and partly automated tools for the diagnosis of melanoma have been tested in clinical studies [4], some of which have successfully entered the healthcare market. In light of the rapid progress made with developments such as deep learning algorithms, we may experience broader application of automated diagnostic tools in healthcare in the near future [9]. In stark contrast to these developments, patient acceptance and trust in such novel, more autonomous technologies have rarely been studied [2]. We therefore decided to combine a multicenter clinical study assessing the diagnostic performance of automated dermatofluoroscopy [5] with a self-completion questionnaire based on the validated "trust in medical technology" (TMT) instrument [8]. In our study, 100 patients were contacted by mail four weeks after dermatofluoroscopy. The response rate of 65 % was high in contrast to other studies using questionnaires sent by mail [10, 11]. Previous publications reported a lower probability of response in patients with a negative outcome in the context of the study, but we found no influence of a melanoma diagnosis on the response rate in our study [12].

Analysis of the questionnaires revealed a broad acceptance and high level of trust in dermatofluoroscopy in particular, and in computer-assisted processes in healthcare in general. Participants indicated that computer-guided dermatofluoroscopy increased their feeling of safety and considered the results of dermatofluoroscopy trustworthy. A similar high level of acceptance and trust was found for the more general statements on computer-assisted diagnoses in healthcare. Interestingly, our extensive search of the literature retrieved only one earlier publication assessing patient acceptance of automated analysis of PSL [2]. In contrast to our study, a markedly lower level of acceptance of 54.5 % was reported for an automated, computer-operated, digital mole analysis system. It is conceivable that patient acceptance in our setting might have been higher because of the extensive information that we provided on the technical background of
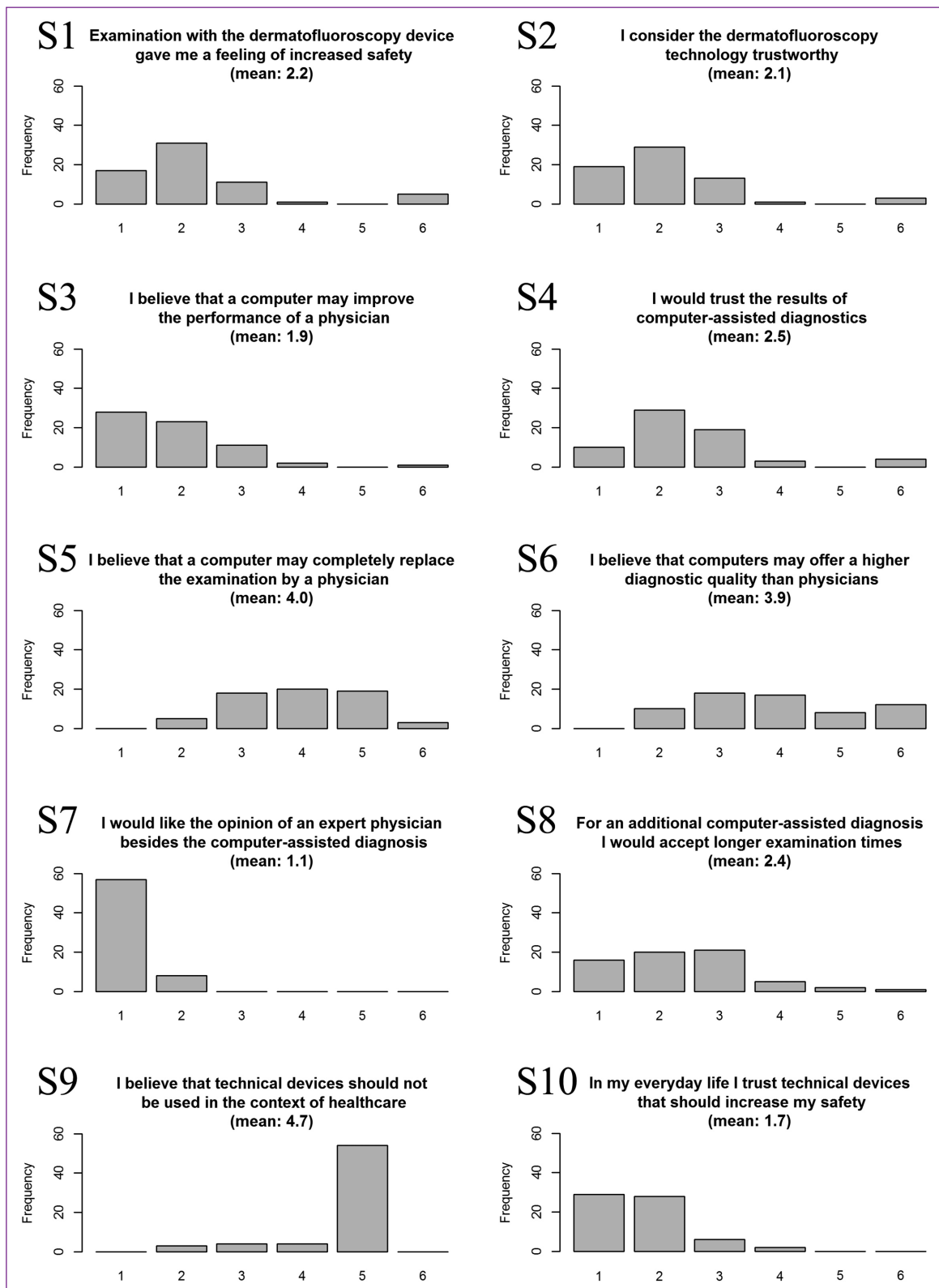
Figure 1 Detailed analysis of 65 questionnaires (statements S1–S10). The level of agreement for each statement (1 = very high, 2 = high, 3 = moderate, 4 = low, 5 = no agreement) is accompanied by the corresponding absolute number of participants. Undecided participants were permitted to indicate "Don't know".

dermatofluoroscopy. In agreement with our data, patients in the previous study [2] mostly rejected the idea of computerized analysis replacing examination by a dermatologist. The sixth statement of our questionnaire asked for the patients' opinion of the relative quality of diagnosis between autonomous computers and physicians in future: "I believe that computers may offer a higher diagnostic quality than physicians". Almost half the patients indicated low or no agreement, while the remaining respondents were undecided or indicated moderate to high agreement. It appears that many patients still struggle with the idea of more autonomous, high-quality, diagnostic processes in healthcare [13], even though autonomous driving or autonomous object recognition systems of vehicles are becoming increasingly evident in public road traffic [14]. It is worth noting that 87.7 % of participants expressed high acceptance of such automated technical devices in everyday life. The highest level of unanimous support was found for the scenario of an expert physician giving his opinion aided by computer-assisted diagnosis. Interestingly, this scenario parallels current legal requirements for autonomous driving, where the (passive) operator of the vehicle must possess a valid driver license, must supervise all autonomous actions of the vehicle, and is responsible for any damage caused while being driven by an automated guidance system [14]. We used a logistic regression model to single out patients' characteristics with a significant influence on the level of agreement to the different statements. In contrast to the earlier study mentioned above, we found a higher level of acceptance of computer-assisted diagnostics in older patients [2]. Our result might be explained by older patients being more concerned with increasing health conditions for which they seek advice or a second opinion [15]. In addition, it is conceivable that older patients are less likely to question or doubt alleged objective diagnostic results, while the younger generation might be more likely to have a critical and questioning attitude towards such information. Finally, we found an increased willingness in male participants to accept longer examinations times for computer-assisted diagnostic procedures. This result is consistent with a trend towards higher overall acceptance of computer-assisted diagnostics in the male participants of our study.

Like all questionnaire studies, our study might have been influenced by various forms of bias, e.g. by response or participation bias. These biases are related to a tendency of respondents to give more positive answers due to their desire to be 'good' experimental subjects. It would also be interesting to assess the influence of the elaborate technical information on the device, e.g. by forming a control subgroup of patients who receive no such technical details.

In conclusion, the results of our study point to a high level of acceptance and trust in computer-assisted and automated diagnostics among patients who were examined with dermatofluoroscopy for PSL with suspected melanoma. However, patients still insist on the opinion of an expert physician. In light of recent achievements in the development of self-learning algorithms, more studies addressing patient acceptance and trust in autonomous diagnostic systems are urgently needed.

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