Dermatology Practical & Conceptual

Lead Time from First Suspicion of Malignant Melanoma in Primary Care to Diagnostic Excision: a Cohort Study Comparing Teledermatoscopy and Traditional Referral to a Dermatology Clinic at a Tertiary Hospital

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ABSTRACT

Introduction: The increasing use of teledermatoscopy in clinical practice has led to demands to evaluate the effects of this new technology on traditional healthcare systems.

Objectives: To study lead times from first consultation in primary care to diagnostic excision of suspected malignant melanoma lesions in traditional referrals to a tertiary hospital-based dermatology clinic compared with mobile teledermatoscopy referrals.

Methods: A retrospective cohort study design was used. Data on sex, age, pathology, caregivers, clinical diagnosis, date for first visit to primary care unit, and date for diagnostic excision were collected from medical records. Patients managed through traditional referral (n=53) were compared with patients managed at primary care units using teledermatoscopy (n=128) regarding lead time from first visit to diagnostic excision.

Results: Mean time from date of first visit at primary care unit to diagnostic excision did not differ between the traditional referral and teledermatoscopy groups (16.2 vs. 15.7 days, median 10 vs. 13 days, p=0.657). Lead times from date of referral to diagnostic excision did not significantly differ (15.7 vs. 12.8 days, median 10 vs. 9 days, p=0.464).

Conclusions: Our study indicates that lead time to diagnostic excision for patients with suspected malignant melanoma managed by teledermatoscopy was comparable and not inferior to that of the traditional referral pathway. If teledermatoscopy is used at first consultation in primary care, it could potentially be more efficient than traditional referral.

Introduction

Sweden has one of the highest incidence rates of cutaneous melanoma in Europe and the incidence is increasing, as in most areas with fair-skinned populations, e.g., North America, northern Europe, Australia, and New Zealand [1]. Diagnosing malignant melanoma at an early stage remains the most important predictor of melanoma survival [2]. Most patients have their first consultation in primary care (PC) and improved management of suspicious pigmented lesions in this setting is needed. Increasing digitalization in healthcare, including teledermatoscopy (TDS), could be a promising instrument for skin cancer care [3-5].

It is well-established that dermatoscopy, in experienced hands, increases diagnostic accuracy for both melanocytic and non-melanocytic lesions [6-13]. Finnane et al. found in their review that teledermatology consistently reduced waiting times for assessment and diagnosis, with high patient satisfaction [14], and studies indicate that lead times for patients with suspected malignant melanoma can be reduced if TDS is used for triage [15-18]. Moreover, double reading of images has been shown to improve diagnostic performance in telemedicine settings [19-21]. The evolution of smartphone-attached dermatoscopes and smartphone applications makes TDS increasingly convenient to use [22,23]. The role of TDS in managing skin cancer, including the lead time from the first visit in PC to diagnostic excision, needs further exploration [4,14].

The region of Stockholm, Sweden, has 2.4 million inhabitants, with access to more than 200 primary care units (PCUs). Patients with suspected skin cancer usually visit a PCU, are evaluated by PC physicians, and, if needed, referred to a dermatologist at either an out-of-hospital or a hospital-based dermatology clinic.

In 2015, in Sweden, a guideline on urgent cancer referral pathways (standardized care (SC) pathways) was implemented for cancer care, including malignant melanoma care [24]. In cases reasonably suspicious of malignant melanoma, a fast-track SC pathway starts and the PC physician labels the referral "SC pathway cutaneous melanoma." The SC pathway's ideal time frame from reasonable suspicion of melanoma to initiation of treatment (diagnostic excision) is seven days.

In 2015, a mobile TDS pilot project was initiated and funded by the Stockholm health authorities at the Regional Cancer Center. In the final implementation of the project, the intention is to include all 200 PCUs in the Stockholm region by 2023.

Objectives

The aim of this study was to investigate potential differences in lead time from suspicion of malignant melanoma to excision when using TDS in PC compared with traditional referral (TR) to a tertiary dermatology center.

Methods

Setting

For the present TDS project, PCUs use a dedicated mobile platform (Dermicus, Gnosco AB, Sweden). From 2015, PCUs in the Stockholm region were recruited. They could participate cost-free. The equipment (dermatoscope and phone) was free for PCs. In 2019 there were two to four physicians active per PCU, with a total of 230 cases per month. PC physicians received an introduction to the equipment and a brief online dermatoscopy course. They chose which lesions and the number of lesions to refer without the involvement of a dermatologist. In the clinic, PC physicians take photos of suspected lesions with a smartphone (iPhone 6S, Apple Inc.), attached to a dermatoscope (Heine ic1; Heine Optotechnik, Herrsching, Germany). An overview, a close-up, and two dermatoscopic images (polarized, unpolarized) are collected and uploaded to a database (Fig. 1,2). The images and background information (e.g., patient age and sex, history of changes and symptoms) are reviewed and dermatoscopic images analyzed through double reading. A consultation report is issued by at least two dermatologists in consensus. The dermatologists are trained in dermatoscopic diagnosis of

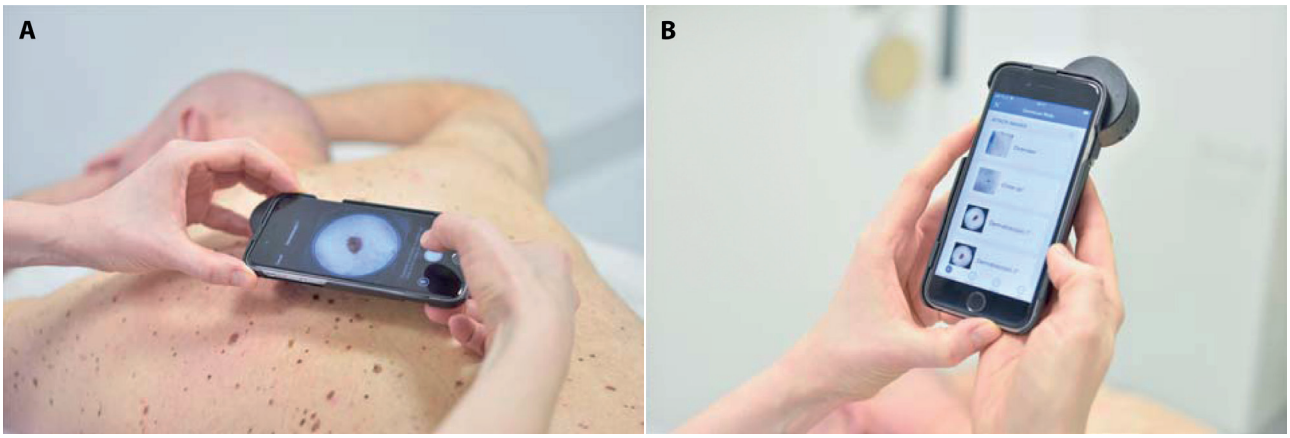

Figure 1. Process of mobile teledermatoscopy as used in the project. The primary care physician examines the patient, takes clinical and dermatoscopic images (A and B), and fills in clinical information which is then packaged together in the mobile app and sent encrypted to a database. Photo by Oscar Segerström, Medicinsk bild, Karolinska Hospital.

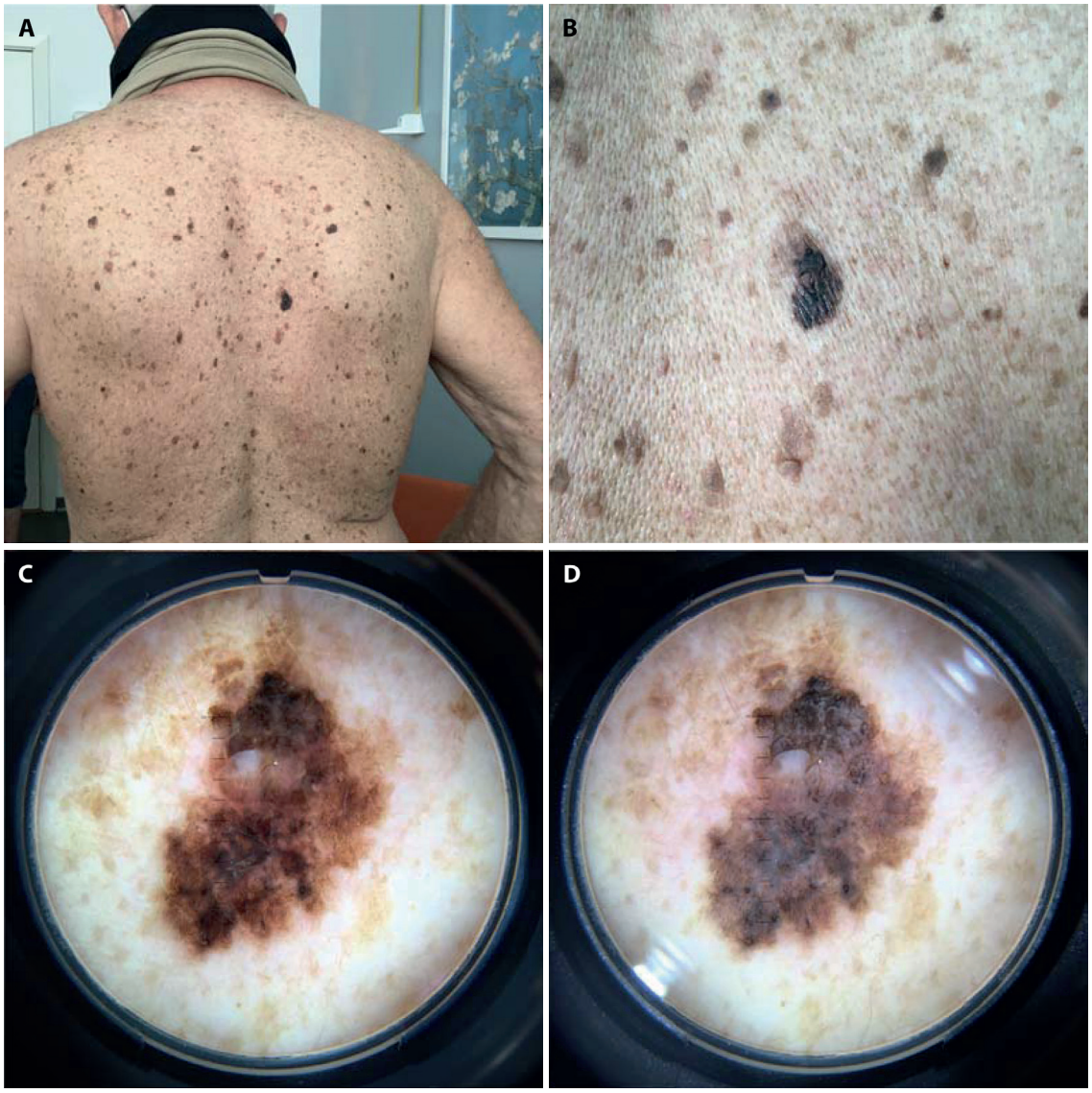

Figure 2. Photographs of a teledermatoscopy case. (A) An overview, (B) a close-up, and two dermatoscopic images ((C) polarized, (D) unpolarized) are collected and uploaded in the mobile application together with background information. Histopathologic diagnosis: Lentiginous malignant melanoma in situ described in pathology report as an extensive atypical junction melanocytic proliferation, lentiginous and nested, with frequent rete fusion, multifocal pagetoid upgrowth and early involvement of adnexal structures. The lesion focally blends with areas of seborrheic keratosis-like epidermal reaction and a small benign intradermal nevus is noted at the periphery of the main lesion.

cutaneous malignancies. The PC physician is provided with a dermatoscopic description of the lesion with a preferential diagnosis and a recommendation for management (Fig. 3). If the lesion is unequivocally benign, no action beyond information to the patient is recommended. In equivocal flat lesions, a short-term digital dermatoscopic follow-up or excision may be recommended. If melanoma is suspected, the recommendation is an urgent excisional biopsy starting the SC pathway. The diagnostic excision is performed at the PC clinic or, if necessary, referred to a specialist.

Study Design and Study Population

All patients managed on the SC pathway due to suspected malignant melanoma 1) at a tertiary dermatology clinic, Södersjukhuset or 2) in the TDS project were recruited to this cohort study. Data were collected from electronic medical records. Patients aged 18 years and older were included. Referrals for specific suspected melanoma lesions that were considered high-priority were selected. Data on sex, age, pathology, caregivers, clinical diagnosis, date of first PCU visit, and date of diagnostic excision, were collected.

Traditional Referral (TR) Group

During the study period from 1 January 2016 to 19 December 2018, 274 patients that were referred to the hospital-based dermatology unit at Södersjukhuset (tertiary DU) and labelled as having suspected melanomas on the SC pathway were identified. Of those 274 referrals, 66 from 29 different PCUs met the inclusion criteria: the purpose of the referral was a specific suspected melanoma that was considered high-priority by the hospital consultant and planned for an in-person visit within two weeks. All referrals in the study were sent in electronic format and prioritized by the dermatologist at tertiary DU on the same date as referrals from PCU were sent.

Teledermatoscopy (TDS) Group

In the period between 1 January 2016 and 26 March 2019, 52 PCUs generated 3,850 individual referrals for TDS. When searching for lesions labelled as suspected melanoma during this period, a total of 200 patients were identified. Fifty-five lesions were excluded based on not being labelled as cases for the SC pathway, 12 had no available electronic medical records, and one was evaluated by only one dermatologist. In all, 132 referrals met the criteria in the TDS group: at least two dermatologists in consensus stated that the suspicion of malignant melanoma was high and that the SC pathway for melanoma was recommended.

Primary Outcome

Lead time (days) from the date of first PCU visit to the date of diagnostic excision.

Secondary Outcome

Lead time (days) from date of referral to tertiary DU or TDS to date of diagnostic excision.

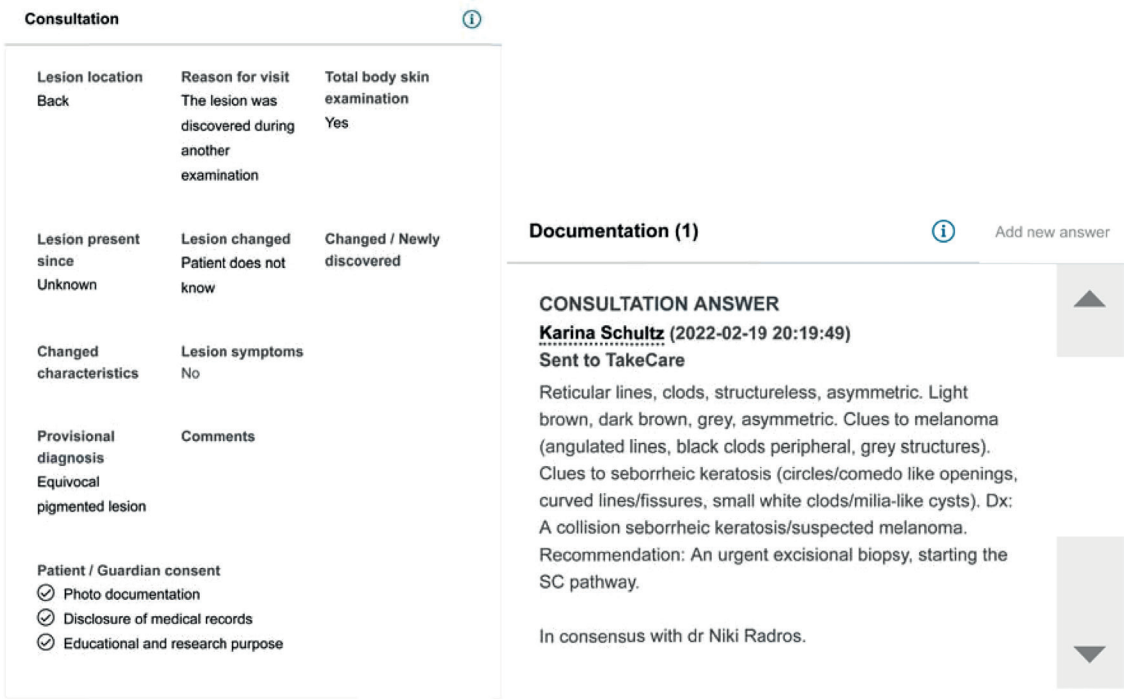

Figure 3. Example of a teledermatoscopy case. The primary care physician fills in clinical information. Two dermatologists assess the case independently and provide a detailed description of the dermatoscopic findings, a provisional diagnosis, and a consensus recommendation for further diagnostic action.

Statistics

Background characteristics are expressed as percentages of the total number of individuals or lesions observed, or mean values and 95% confidence intervals (CIs). Lead times were not normally distributed in the study population and are presented as medians with interquartile ranges (IQRs). P values were calculated with the two-sample Wilcoxon-Mann-Whitney rank-sum test or chi-squared test (dichotomous variables), and $p < 0.05$ was considered significant. All statistical calculations were performed with Stata statistical software (StataCorp 2019. *Stata Statistical Software: Release 16*. College Station, TX: StataCorp LLC).

Ethics

Ethical approval was obtained from the Swedish ethics committee (2019-01290).

Results

A total of 198 patients (one unique lesion per patient) were included in the study, 66 in the TR group and 132 in the TDS group (Fig. 4). The background characteristics and a summary of diagnoses are shown in Tables 1 and 2, respectively. No significant differences were observed in age, sex, lesion diameter, or the proportion of histopathologically confirmed melanomas. The proportion of invasive melanoma was significantly larger in the TR group than in the TDS group (p=0.028) and invasive melanomas were significantly thicker in the TR group (p=0.005). The proportion of melanoma *in situ* was larger in the TDS group (p=0.036). Among excised lesions, five were of non-melanocytic origin in the TR group and nine in the TDS group (Table 2). In the TR group, five seborrheic keratoses were confirmed by partial biopsy, but none were considered high-priority (SC pathway) at in-person visits at the tertiary DU.

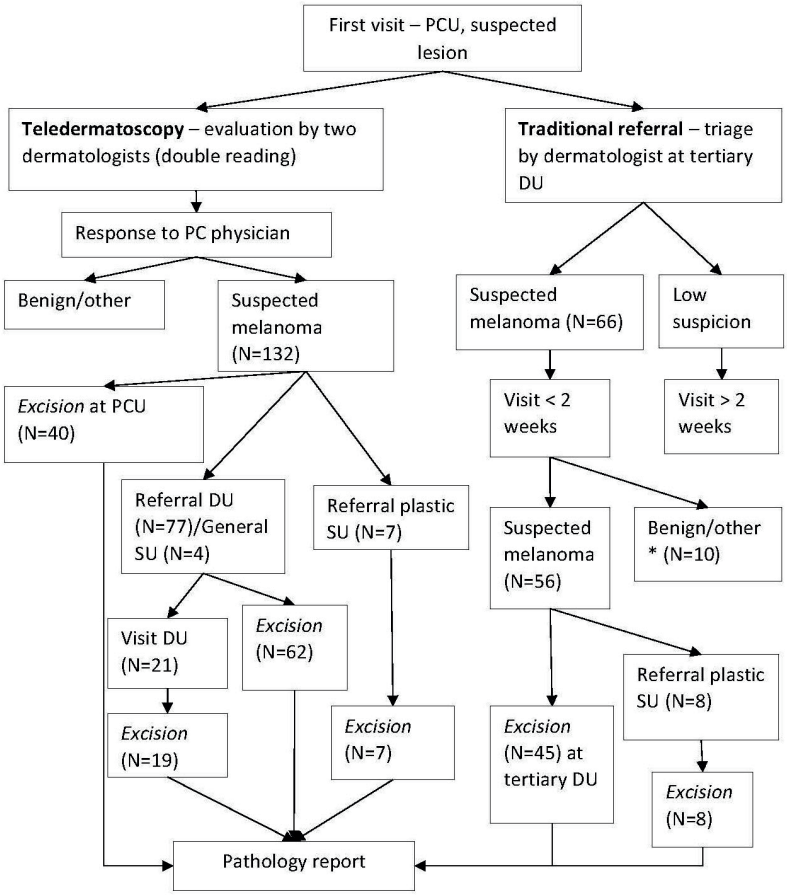

Figure 4. Study flowchart. DU – dermatology unit, PC – primary care, PCU – primary care unit, SU – surgery unit, SC – standardized care, tertiary DU – Södersjukhuset dermatology unit.

* SC pathway ends at face-to-face visit.

Table 1. Characteristics of the study population.

	Traditional referral (n=66)*		Teledermatoscopy (n=132)**		
	Mean	95% CI	Mean	95% CI	P value
Age (years)	61.0	57.0–64.9	56.1	53.4–58.9	0.054
	Proportion	95% CI	Proportion	95% CI	
Female sex (%)	42.4	30.3–55.2	53.8	44.9–62.5	0.132
Proportion of melanoma	54.5	42.2–68.9	54.5	45.9–63.2	1.000
Proportion of in situ melanoma	**19.7**	**10.9–31.3**	**34.1**	**26.1–42.8**	**0.036**
Proportion of invasive melanoma	**34.8**	**23.0–46.7**	**20.5**	**13.5–27.4**	**0.028**
	Mean	Range	Mean	Range	
Thickness of invasive melanoma (mm)	**1.35**	**0.30–4.50**	**0.74**	**0.20–2.15**	**0.005**
Max lesion diameter (mm)	11.4***	2–30	9.4***	2–30	0.057
Lesion localization					
	Number	Proportion (%)	Number	Proportion (%)	
Head	8/66	12.1	10/132	7.6	
Arms (including shoulders)	13/66	19.7	20/132	15.2	
Legs	16/66	24.2	26/132	19.7	
Trunk (including neck, gluteus)	29/66	43.9	76/132	57.6	

CI: confidence interval *Traditional referral: 66 lesions, 36 melanomas (13 *in situ*, 23 invasive). **Teledermatoscopy: 132 lesions, 72 melanomas (45 *in situ*, 27 invasive). ***There were missing values regarding diameter of the lesion: traditional referral group (n=6), teledermatoscopy group (n=3). P values calculated with the chi-squared test (dichotomous variables) or the two-sample Wilcoxon-Mann-Whitney rank-sum test. Significant differences marked in **bold**.

Table 2. Diagnoses of the excised lesions (suspected malignant melanoma at first visit in primary care) among the study participants.

	Traditional referral (N=66)					Teledermatoscopy (N=132)			
Diagnosis	**Excised**	**Partial biopsy**	**Clinical evaluation**	**Standard care pathway***	**Total**	**Excised**	**Partial biopsy**	**Clinical evaluation**	**Total**
Melanoma invasive	23	0	0	23	23	27	0	2**	29
Melanoma in situ	13	0	0	13	13	44	1	0	45
Severe dysplastic nevus	2	0	0	2	2	7	0	0	7
Melanocytic nevus	10	1	0	10	11	38	0	1	39
Seborrheic keratosis	3	5	1	3	9	2	0	0	2
Squamous cell carcinoma	0	0	0	0	0	0	0	0	0
Basal cell carcinoma	1	0	0	1	1	0	0	0	0
Spitzoid lesion	1	0	0	1	1	3	0	0	3
Other***	1	3	2	3	6	7	0	0	7

* Lesion evaluated as highly suspected malignant melanoma at face-to-face visit at a tertiary dermatology unit (n=53) ** Patient declined excision. *** Traditional referral group: Epidermal hyperplasia, angioma, lichenoid keratosis, paronychia, subungual bleeding, pseudocyst. Teledermatoscopy group: Atypical lentiginous lesion, lentigo benigna, lichenoid keratosis, angioma, fibrous histiocytoma, basal melanosis.

TR Group Analysis

Of the 66 patients with a referral from PCU, and labelled high-priority by a dermatology consultant, 56 were assessed as eligible for the SC pathway at an in-person visit at the tertiary DU. In ten cases, the SC pathway was aborted at in-person visits due to the lesion not meeting the criteria of suspected melanoma; one was of melanocytic origin (melanocytic nevus) and was excised, while the rest had other diagnoses. Three lesions were managed through partial biopsy at the first visit and not scheduled for diagnostic excision. In the TR group (n=53), median lead time from first visit at PCU to diagnostic excision was 10 days (IQR 6–20; mean 16.2). When excluding eight patients that were referred to a plastic surgery unit (SU), the median lead time was 10 days (IQR 6–14; mean 11.4).

TDS Group Analysis

Of 132 TDS referrals assessed as suspected melanoma, 128 were excised (Fig. 4). Excision was performed at PCU in 40 cases. Seventy-seven cases were referred to a dermatology unit (DU) for excision. In seven cases, the PCU chose to refer the patient to a plastic SU due to lesion location and size. Four lesions were referred to a general practice surgeon. Reasons for lesions not being excised (n=4): patients declined excision/further treatment (n=2), referral to a DU where another dermatologist ended the SC pathway, viewing the lesion as benign (n=1), lentigo maligna treated with Grenz rays [25] after biopsy instead of excision (n=1).

Median lead time from the first visit to diagnostic excision was 13 days (IQR 6–19; mean 15.7) among all excised lesions in TDS (n=128). One patient's referral was neglected, with late management (time to excision 156 days); the case was described as an invasive melanoma in the pathology report. After exclusion of that case, median lead time was 13 days (IQR 6–19; mean 14.6). Some patients were rescheduled at the PCU visit and received a separate appointment for TDS (n=26), which resulted in extended lead time to diagnostic excision. Patients who got TDS at their first visit (n=101) had significantly shorter lead time ($p<0.001$) than those who were rescheduled: median 10 days (IQR 6–16; mean 12.6) vs. median 18 days (IQR 13–29; mean 22.3). Patients with a difficult site for excision of malignant melanoma were referred to a plastic surgeon (n=7). Median lead time for these patients was 25 days (IQR 16–43; mean 30.7). Patients with excision at other units (DU or general SU, n=80) had comparable lead times, median 13 days (IQR 8–17; mean 13.9). The median lead time for patients with surgery performed at a PCU (n=40) was significantly shorter ($p=0.013$) than for patients receiving surgery at other units, including plastic SU (n=87), 7.5 days (IQR 3–19.5, mean 13.2) vs. 13 days (IQR 8–19, mean 15.2).

Comparison of TR and TDS Group Lead Times

Including all excised SC pathway lesions in both cohorts (n=181), the median lead time from the first visit to diagnostic excision was 12 days (IQR 6–19; mean 15.8) and from referral to excision 10 days (IQR 6–16; mean 13.6).

Median lead times from first PCU visit to excision were comparable ($p=0.657$) between the TR group (n=53, 10 days, IQR 6–20; mean 16.2) and the TDS group (n=128, 13 days, IQR 6–19; mean 15.7). Median lead times from the date of referral sent from PCU to time of excision were also comparable ($p=0.464$): TR 10 days (n=53, IQR 6–20; mean 15.7) vs. TDS 9 days (n=128, IQR 5–15.5; mean 12.8).

When comparing the TR and TDS groups and excluding the neglected patient (lead time 156 days), times from the first visit to excision had a median of 10 vs. 13 days ($p=0.716$) and times from referral to excision were not significantly different (median 10 vs. 9 days, $p=0.412$).

For histopathologically confirmed malignant melanomas, the median lead times from the first visit to excision were comparable ($p=0.905$) in the TR (n=36) and TDS groups (n=71): 13 days (IQR 6.5–22; mean 19.1) vs. 14 days (IQR 7–18; mean 16.8), as were the median lead times from referral to excision ($p=0.166$): TR 12.5 days (IQR 6–22; mean 18.4) vs. TDS 10 days (IQR 4–15; mean 13.2).

Discussion

In this study from Stockholm, patients with suspected malignant melanoma identified in PC had a median lead time of 12 days (IQR 6–19; mean 15.8) from first consultation to diagnostic excision. We found that the use of TDS referral pathways in PC was at least as efficient regarding lead time as TR to a well-organized hospital clinic specialized in cutaneous cancer care. The study identified an organizational procedure that prolonged the lead time when using TDS. If TDS were optimized by avoiding internal rescheduling for TDS at the PCU, it could have an even shorter lead time to excision. The impact of TDS on lead time might be of even greater value in rural areas. Furthermore, our findings showed that lead time in both cohorts was comparable to the standards recommended in international guidelines presented in the Australian Optimal Care Pathway for people with melanoma and the UK Government two-week rule for the skin cancer referral pathway [26,27]. The lead times in our study are favorable compared with those in other settings [16,17]. However, the Swedish SC pathway's ideal time

frame of seven days to excision was not achieved in either the TR or the TDS group. The shortest lead times were observed for patients with surgery performed at a PCU.

In our analyses of histopathologcally confirmed malignant melanoma excised at a PCU (n=20), median time from referral for TDS to excision was 4 days (range 1–47) and from first PCU visit to excision 7.5 days (range 1–47). Similarly, Wikström et al. have recently shown that patients in Stockholm with malignant melanoma had a significantly shorter median lead time to diagnostic excision when surgery was performed by a general practitioner (GP) (5 days) when compared with private dermatology/surgery or university clinics (16 and 12 days, respectively) [28]. Both studies indicated that PC in Stockholm was more effective regarding lead time to excision than when patients were referred for excision. If TDS is used properly, the lead time to excision for patients with suspected malignant melanomas could be reduced even more. Other studies have shown that lead time can be reduced by using TDS [15-18,29]. As pointed out in the literature review by Finnane et al., actual waiting times vary significantly between different studies [14]. Congalton et al. demonstrated the ability of TDS to reduce wait times in a virtual lesion clinic (VLC), a skin imaging center, in New Zealand [16]. Patients were referred by a GP to a VLC, where TDS was performed. The median waiting time between referral and VLC assessment was 9 days, compared with 26.5 days for standard outpatient assessment by a dermatologist. VLC patients underwent excision earlier than patients undergoing a standard assessment. Median time to excision of a suspected melanoma was 40 days from VLC assessment. In another consecutive study from New Zealand, Sunderland et al. showed that a hybrid e-referral system, where an experienced surgical oncologist selected the management option or referred suspected melanomas for TDS, could reduce the number requiring excision [30]. In a TDS project in Belgium (Telespot), Damsin et al. found a median delay of 11 days between TDS diagnosis and treatment of high-priority lesions, which was seven times shorter than the conventional care pathway [17]. Morton et al. set up a photo triage center and reduced mean waiting times to intervention for melanoma from 39 to 36 days [29]. In both Congleton et al. and Morton et al., patients were lost to follow-up since they did not show up for the photo session (10% and 22%, respectively). This highlights why TDS at a first visit is important, and when TDS is performed at the first PCU visit, the risk of no-shows can be eliminated.

Studies on the timeline from a patient first noticing a lesion to consultation and excisional biopsy have not shown any impact on Breslow thickness, though they have shown that patient delay (pre-presentation time) makes up the largest proportion of the delay [31,32]. There are studies indicating that time to excision can affect the prognosis, at least for nodular melanomas: five- and ten-year disease-specific survival both decreased by 14.4% in patients treated after a potential delay of 3 months [33]. Radical diagnostic excision is probably the most important therapeutic intervention in a localized disease stage, and studies on time to subsequent wide excision have reported somewhat contradictory outcomes on prognosis [34,35]. The need of improving the prevention and outcomes of skin cancer is discussed in the summary by Garbe et al. [36]. They highlight that better training of GPs/PC physicians in skin cancer detection and better coordination of the patient care pathway from the GP/PC physician are necessary. The threshold for patients seeking help for a worrisome skin lesion may be reduced by convenient, easily accessible, well-organized expertise – for instance through TDS – in PC. We observed that PC physicians initially referred banal lesions for TDS evaluation, but this gradually advanced to predominantly complex referrals. As discussed in the review of Fee et al., one of the barriers to the use of dermatoscopy in PC is lack of training [37]. The educational value of TDS in PC could be significant and is not well-studied. Furthermore, TDS is still not included in European residency programs. To date, some TDS projects were carried out, for training purposes (i.e., early melanoma recognition) and showed that residents/novices reached a higher learning curve and accuracy compared with older/experts, especially with mobile tools [38,39]. In addition, the covid pandemic has stressed the importance of being able to manage TDS tools.

The use of dermatoscopy by general practitioners in conjunction with the value of TDS could significantly improve the early detection of melanoma. It may, in part, explain the detection of a higher proportion of in situ melanomas and melanomas with a lower Breslow thickness in the TDS cohort. Further, there is evidence that melanomas detected by dermatologists are thinner than those detected by non-dermatologists [40]. An alternative explanation is the involvement of selection bias where the more obvious melanomas are referred to either a dermatologist or for excision (without TDS consultation), while PCUs use TDS for more equivocal lesions. If this is true, then the number needed to excise for benign lesions may decrease with TDS.

This paper compares two ways of processing patients with suspected melanoma lesions, initially evaluated in PC. We did not find any significant difference in lead times between the TR pathway and the TDS pathway. When analyzing teledermatoscopy separately, we could conclude that there was potential to optimize lead times by using TDS at a first appointment, rather than rescheduling specifically for TDS – and also, when possible, performing diagnostic excision in a PCU. In Stockholm, TDS is becoming one of the key instruments in PC, with PC physicians enlisting the aid of dermatology specialists. Although studies have recognized

that TDS can be an effective tool to improve skin cancer care, research has yet to closely investigate its role in varied settings, such as urban or rural.

Strengths and Limitations

The major strengths of this study are the cohort design and the inclusion of a cohort of patients treated with standard healthcare (TR group) for comparison of lead times. However, it is a limitation that we included only one tertiary center, making it difficult to generalize our findings to healthcare systems in other settings, such as other regions in Sweden, remote or rural areas, or other countries with unstructured tracking of suspicious cancer. Another limitation is that the study was conducted at the time of a pilot TDS project, and therefore not representative of how efficient it will be after implementation.

Conclusions

Lead time from a first PCU visit to diagnostic excision in a TDS urgent referral pathway in PC was comparable to that of a traditional urgent referral pathway to a well-organized hospital clinic. If TDS is used at the first PC consultation, the lead time to diagnostic excision of suspected melanomas could be shorter than it is with the standard referral pathway.

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