

STORE-AND-FORWARD TELEDERMATOLOGY USING MOBILE PHONES: CLINICAL EFFICACY IN A RURAL PRIMARY HEALTHCARE CENTRE FREE CLINIC SETTING

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Abstract

Background: Technological advances increase the feasibility of mobile-phone teledermatology (mdermatology). By saving time and costs, underserved areas lacking dermatologists may benefit greatly. Objectives: To assess the clinical mobile-phone efficacy of store-and-forward mdermatology compared to face-to-face consultation. Methods: Patients from a rural health centre in Batangas were randomised to either mdermatology or face-to-face group. In the mdermatology group, a general practitioner (GP) assessed patients, took photographs using a cell phone camera and sent these via e-mail accessed via the GP's mobile phone to the mdermatologist's mobile phone. In the face-to-face group, the GP assessed patients and then referred them to the faceto-face dermatologist. Both the mdermatologist and face-to-face dermatologist provided assessments and plans for patients in their respective groups. Clinical outcomes were assessed after two and four weeks. Results: A total of 123 patients were included, with 60 participants in the mdermatology group and 63 in the face-to-face group. In both groups, most participants improved. There were no significant differences in clinical outcomes assessed by GPs (p=0.074), dermatologists (p=0.172), or participants (p=0.405). The diagnostic strength of agreement between the GP and the dermatologist differed between the two groups (Cohen's $\kappa=0.5775$ vs. 0.2735), but management concordance was similar Store-and-forward (p=0.775). **Conclusion:** teledermatology using mobile phones in the dermatologic management of patients in a rural primary healthcare centre free clinic setting is feasible. This study did not find mobile

teledermatology inferior to face-to-face consultation.

Keywords: telemedicine; mhealth; mdermatology; rural health; treatment outcome; efficacy; concordance.

Introduction

Telemedicine can improve access to specialty care and its use has been facilitated by rapid technological advances. Dermatology, due to its visual nature and ability to be captured in images, has made teledermatology an ideal use of telemedicine. Teledermatology is defined as the delivery of dermatologic care via information and communication technology.¹ It expands the reach of a dermatologist to those lacking access to specialist care. This is especially important in many Asian countries where the ratio of dermatologists to overall population is very low.²

Store-and-forward (SF) teledermatology uses asynchronous data transmission of digital photographs and patient information for review at a later time in lieu of live-interactive/videoconferencing teledermatology. There is consistent literature evidence that SF teledermatology is economic, reliable and accurate in diagnosing skin disease, when compared with face-toface (FTF) consultations.³ It improves access to care, with high levels of patient and provider satisfaction, and can also lead to shorter waiting times and fewer specialist referrals.⁴ However, traditional SF teledermatology can be tedious, time-consuming and involves use of costly equipment not available in most rural communities. With the large coverage and rapid advances of mobile phone technology, mobile phones may provide a feasible, cheaper way of delivering dermatologic care to underserved areas of the

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Philippines. Mobile phones have been shown to be feasible as teledermatology tools. Photographic images taken with cameras in smartphones have yielded high diagnostic agreement ranging from 61-80% and high management concordance, ranging from 81-98%. Mobile teledermatology in the developing world has also been promising, with diagnostic agreement higher than 70% in Egypt and Ghana and satisfactory management in 76% in a pilot study in Uganda.⁵

A search of the Health Research and Development Information Network (HERDIN) database, the national health research repository of the Philippines, as well as searching journals of the Philippine hand Dermatological Society, yielded only two studies reporting SF teledermatology in the Philippines, both limited to clinics and to a single institution. In 2001, Lansang (2001) assessed digital photographs with an image resolution 800x600 from 99 patients and found a diagnostic concordance between face-to-face consultations of 77.3% - 95.2% (Kappa 0.73-0.92).⁷ Using more sophisticated digital cameras in 2008, Ramirez et al reported diagnostic concordance of 73.8%, 73.4% and 75.7% for images taken with 2MP, 3.2MP and 5.0MP cameras.⁸

While there has been a wealth of studies that have proven that diagnostic and management decisions made via SF teledermatology are reliable and accurate, its impact on clinical course has been less documented.9 A PubMed search using "clinical course outcome AND teledermatology" yielded only four papers, while a search string "clinical outcomes AND mobile phones AND teledermatology" identified just one. In a review of research evidence on teledermatology in 2015, only four studies investigated the effects of teledermatology on health outcomes from 2005 to 2015, three of which were SF teledermatology.¹ These studies showed that there was either no significant difference in the SF teledermatology outcomes between and conventional consultation^{3,10,11} or that SF teledermatology afforded improved outcomes in patients.12,13

The rapid advances in mobile phone technology and connectivity may make this a more feasible and practical way of conducting SF teledermatology. Over time, costs have been decreasing, mobile phone coverage has been increasing, and Internet connectivity has been improving. In 2015, the number of mobile phone subscribers (active SIM cards) in the Philippines reached 113 million, which is 114% of its almost 100 million population.¹⁴ Broadband Internet subscription

has also begun to surge. Although broadband penetration in the Philippines is now still at just 11% of the population, local telecommunications companies have begun to deploy 4G LTE mobile services, with their 4G network covering more than 85% of the population.¹⁵

This study evaluates the feasibility and efficacy of mdermatology in the management of patients at a free, rural, primary healthcare centre. If validated, the findings will lay the foundation for teledermatology services in public health facilities and underserved communities. The satisfaction and acceptability of mdermatology to patients and general practitioners, duration of consultation, and cost of mobile phone teledermatology will be reported separately.

Methods

This was a parallel group, randomised controlled trial. A cross-sectional survey was also done using selfadministered, face-validated questionnaires to determine patient-assessed clinical outcomes. This study was approved by the Ethics Review Board of the University of the Philippines and all patients provided written informed consent.

The study was performed in the Rural Health Unit (RHU) 1 of San Juan, Batangas, the unit with the highest load of patients among the RHUs in the community. To recruit subjects, Free Skin Clinic Days at the RHU were announced one month prior to the study. Participants were local residents with a skin lesion belonging to any of the five morphologic classes: skin-coloured, pigmented, hypopigmented/depigmented, erythematous, or vesiculobullous, who were able to give informed consent (or with consent of a legally acceptable representative if younger than 18 years or legally incapacitated). Those with lesions found on hairy areas (which would have poor image quality), or those who declined to participate in the study were excluded. A sample size of 79 per treatment group was estimated to achieve 80% power to detect a non-inferiority margin difference between the group proportions of -0.20. The target sample size was 88 per group after adjustment for a 10% drop-out rate.

Two dermatologists participated in the study. Both had at least 10 years clinical experience and were graduates of the same residency training programme. One served as the mdermatologist and the other served as the face-to-face consultant. The referring GPs were two health centre physicians with no additional formal training in dermatology. A dermatologic photography workshop and training session was conducted for the referring GPs prior to the study, teaching them standard clinical case composition using a mobile phone to send encrypted e-mail referrals to the mdermatologist. The mdermatologist was also instructed on the standard response to consultation via text messaging.

Patients were randomised to either face-to-face consultation or mdermatology consultation during the first Skin Clinic Day. A second and third Skin Clinic Dav were held two and four weeks after initial baseline visits in order to assess clinical outcomes of patients. Computer-generated randomised numbers were used to assign patients to the two treatment groups. To minimise variability, patients were grouped according to common dermatoses in the community: eczemas, bacterial, fungal and viral infections, infestations, acne, papulosquamous disorders, neoplasms, and others. Block randomisation by dermatoses group was done per arm. A third party held patients' group assignments in sequentially-numbered, sealed, opaque envelopes. Codes were assigned to patients for anonymity.

mDermatology

For those randomised to an mdermatology consultation, the referring GP filled out the Standardised Medical Form (SMF) for Physician Referring to MDermatologist, which contained the patients' case details, presumptive clinical diagnosis and a proposed treatment based on the GP's history-taking and physical examination. A standardised mobile phone e-mail referral containing the photographs of the patient's lesion and case details was then created for each patient and sent to the mdermatologist through an open network.

Images were taken without flash using a Samsung Galaxy SIII phone, equipped with an 8MP (3264x2448 pixel) camera, provided to the referring GP. Autofocus and macro-mode for far and close-up views were used, respectively. Diffuse, indirect lighting was used to illuminate the field. Patients were placed against a non-reflectant flat surface background. Images were stored in a secure digital card. Wireless 3G mobile Internet was used to transmit images and referrals from the mobile phone to a designated encrypted, password-protected, secure e-mail accessible only to the mDermatologist. SMS text messaging was used by the mdermatologist to reply to the e-mailed referrals.

The times required to examine the patient, capture digital images, create the standardised e-mail referral, and forward data via the Internet to the mdermatologist were recorded. The time of arrival of the e-mail to the mdermatologist's mobile phone was recorded on the SMF for MDermatologist by the mdermatologist, who then reviewed the history and photographs, provided a diagnosis and management plan, and recorded these. The sufficiency of the images for clinical evaluation and image quality was assessed as insufficient, sufficient, good, or very good, and recorded. The diagnosis and management plan were sent back to the referring GP. The referring GP indicated on the patient's SMF for Physician Referring to MDermatologist whether or not he/she agreed with the telediagnosis and followed the mdermatologist's management recommendations.

Face-to-face dermatology

For those randomised to FTF consultation, the referring GP filled out the SMF for Physician Referring for Faceto-Face Consultation containing the same variables as those in the mdermatology group based on his/her history-taking and physical examination. The patient was then directed to the FTF dermatologist for an independent history and physical examination. Findings, diagnosis and management were recorded and the patient was then directed back to the referring GP for management. The referring GP then indicated whether or not he/she agreed with the diagnosis and followed the FTF dermatologist's management recommendations. If GP did not agree with diagnosis and management of FTF dermatologist, GP's management plan was followed.

To facilitate compliance with the management plan, the investigators provided the diagnostic tests and medications for both groups.

The primary outcome was the dermatologistassessed clinical outcome of patients two and four weeks after initial consultation. The mdermatologist's assessment was based on the second and third e-mail referrals sent by the GP at follow-up visits two and four weeks after initial assessment. The FTF dermatologist's assessment was based on the patient's consultation with a dermatologist at follow-up visits two and four weeks after initial consultation. The doctors and patients rated outcomes using a three-point rating scale (1=improved, 2=no change, 3=worse).

Computation of the effects of the interventions (mdermatology vs. face-to-face consultation)

The relative risk reduction (RRR), absolute risk reduction (ARR), number-needed-to-treat (NNT), and 95% Confidence Interval (CI) were computed using the negative endpoint "failure of intervention". If the 95%



CI of RRR or ARR include the null value of zero, then the effects were interpreted as not significant.

Failure of Intervention was defined as worsening or no change in skin disease as assessed by the dermatologist and/or the patient-assessed worsening or no change in skin disease. Successful Intervention was defined as improvement of skin disease assessed by the dermatologists and the patient. Sensitivity analysis using the worst case scenario was done to assess the effect of drop-outs.

Secondary outcomes included GP-assessed clinical outcome of their patients two weeks and four weeks after the initial consultation, patient-assessed clinical outcome two weeks after the initial consultation measured by face-validated questionnaires, and the difference in diagnostic agreement between dermatologists and referring GPs from both treatment groups. Diagnostic agreement was calculated as Cohen κ values with 95% CI, and differences were analysed as simple proportion agreements with 95% CI. The level of diagnostic and treatment agreement between referring GPs and dermatologists was rated as complete agreement, partial agreement, or disagreement. An intention-to-treat analysis was performed. Stata 12 was used for statistical analyses, with alpha set at 5%.

Results

One hundred and thirty-three people met the inclusion criteria, of whom ten declined to participate, and 60 people were allocated the mdermatology group and 63 to the face-to-face group. There were 18 people lost to follow-up in the mdermatology group and 17 in the FTF group leaving 42 and 46 cases respectively for analysis. The target sample size was not achieved despite recruitment efforts during two free clinics. The demographics of the enrolled patients are shown in Table 1. There was no significant difference in the distribution of diseases between both groups (Fisher's exact test, p = 0.228).

Clinical Outcomes

There was a trend that FTF dermatology led to better patient clinical outcomes than mdermatology as assessed by GPs (68.3% vs. 53.3%), dermatologists (68.3% vs. 55%), and patients (69.8% vs. 61.7%), but the differences were not significant. Based on intentionto-treat analysis, the FTF group had a higher proportion with improved skin disease across all assessors (GPs, dermatologists, patients) but these differences between groups were not significant. (Table 2)

	FTF	mDerm
	n=63	n= 60
Gender		
Male	32	14
Female	31	46
Mean Age	32.6	31.4
Median age	34	32
Age range	10m - 72 y	6m - 84 y
Travel time to clinic		
<40 min trip	63	57
>40 min by car	0	3
Mode of transport		
Jeep	1	2
Tricycle	62	57
No data	0	1
Occupation		
Housewife	0	10
Gov. Employee	8	8
None	25	28
Others	30	14
Dermatoses		
Acne	2 (3.3%)	3 (4.8%)
Bacterial	3 (5.0%)	5 (7.9%)
Eczema	10 (16.7%)	10 (16.0%)
Fungal	11 (18.3%)	7 (11.1)
Infestations	13 (21.7%)	7 (11.1)
Others	21 (35.0)	25 (39.7%)
Papulosquamous	0	4 (6.4%)
Viral	0	2 (3.2%)

Table 1. Clinical outcomes one month after initialconsult "last observation carried forward".

The numbers of successful and failed interventions are shown in Table 3. Although there were more failed events in the mdermatology group, this was not significant (p=0.098).

Relative risk reduction was -141 (95%CI:-536.2 - 8.7), the absolute risk reduction was -15 (95%CI:-31.4 - 0.7) and the number needed to treat was -6.5. The 95% CI for NNT is difficult to compute since the ARR extends from a negative number to a positive number. In summary, in the intention-to-treat analysis, there were more bad events in the mdermatology group compared to the face-to-face group, but the results were not significant.

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	Face to Face		mDermatology			P value			
	GP	FTF	Patient	GP	mDerm	Patient	GP	Derm	Patient
	%	%	%	%	%	%			
Improved	68.3	68.3	69.8	53.3	55.0	61.7			
Unchanged	4.8	4.8	3.2	13.3	13.3	6.7	0.074	0.172	0.405
Worse	0	0	0	5.0	1.7	0	0.074	0.172	0.405
Lost	27.0	27.0	27.0	28.3	28.3	28.3			
No data†	0	0	0	0	1.7	3.3			

Table 2. Clinical outcomes one month after initial consult "last observation carried forward".

*All lost to follow-up included in analysis

[†] For missing values. last observation carried forward was used.

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Diagnostic and management concordances

The GPs and dermatologists had partial to complete agreement in diagnosis for the majority of cases: 59% in the FTF group and 70% in the mdermatology group. This difference was not significant between the two groups. The kappa value for the mdermatology group was 0.57 and 0.27 for the FTF group. In both groups there was over 95% concordance of the management plan between the GP and the dermatologist.

Table 3. The numbers	of successful	and failed	interventions
per group.			

	Event failures	Event successes	Total
mDerm Group	11	31	42
FTF Group	5	41	46
Total	16	72	88

Discussion

To date, only five studies have recorded the clinical course of patients seen through teledermatology.^{3,10-13} These studies showed that there was either no significant difference in the outcomes between conventional consultation and SF teledermatology,^{3,10,11} or that SF teledermatology afforded improved outcomes.^{12,13}

In this study, although FTF dermatology appeared to have better patient clinical outcomes than mdermatology, as assessed by GPs, dermatologists, and patients, the differences between the two groups were not significant. This is consistent with studies by Pak et al.¹⁰, Watson et al¹¹, Whited et al³ which showed no significant differences in outcome between the two groups. Two other studies reported improved outcome with SF teledermatology group.¹²⁻¹³ (Table 4)

With 123 study participants, the power achieved by the study is approximately 68.3%. Based on intentionto-treat analysis, the FTF group had a higher proportion of patients with improved skin disease across all assessors (GPs, dermatologists, patients) but these differences between groups are not significant. Our study showed clinical outcomes of mdermatology and FTF consultation were comparable two weeks and one month after the initial consultations and shows that mobile SF teledermatology is promising and consistent with previous literature investigating the clinical outcome of SF teledermatology.

In this study, the diagnostic concordance between the dermatologists and GPs from both groups reflected the baseline dermatologic knowledge of the GPs. This analysis differs from other studies which compared two dermatologists' diagnoses to evaluate whether teledermatology was a reliable diagnostic tool.8,16-19 However, management concordances were not significantly different comparing both groups. This could indicate that primary care physicians, skilled or not, rely heavily on specialist's opinions regarding dermatologic skin conditions. In a study by Feldman et al., skin disorders had higher referral rates from primary care providers compared to other medical conditions, which could reflect their difficulty in managing skin problems.²⁰ This emphasises the value of teledermatology in handling dermatology cases in a rural health care setting.

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Reference	Country	Study Design	N=	Clinical Outcomes
Pak et al, (2007) ¹⁰	United States	RCT	776	TD: 64% (I), 33 (NC), 4% (W) FTF: 65% (I), 32% (NC), 3% (W) P= 0.71, Fisher's exact test
Eminovic et al., (2009) ¹²	Netherlands	Multicentre cluster RCT	369	TD: 40/200 (20%) (I) FTF: 7/169 (4%) (I)
Watson et al, $(2010)^{11}$	United States	RCT	151	No significant difference in mean reduction in acne lesions between asynchronous visit vs. office care
Ferrandiz et al, (2012) ¹³	Spain	Descriptive longitudinal study	201	Mean Breslow thickness of melanoma subjects significantly less in TD group compared with patients in the non-TD group (mean, 1.06 vs 1.64 mm, P=.03);
Whited et al, $(2013)^3$	United States	RCT	261	No significant difference between FTF and SF TD clinical course outcomes
Present study (2016)	Philippines	RCT	123	GP-assessed improvement: 68.3% (FTF) vs. 53.3% (mD). Dermatologist-assessed improvement: 68.3% (FTF) vs. 55% (mD). Patient-assessed improvement: 69.8% (FTF) vs. 61.7% (mD)

Table 4. Comparison of clinical outcomes for published trials of store-and-forward (S&F) teledermatology.

I = improved; NC = no change; W = worse; RCT = randomised controlled trial; TD = teledermatology; FTF = face-to-face; GP = general practitioner; mD = mobile dermatology.

Since underserved areas have different expectations and satisfaction levels compared to more developed areas, our results may be applicable only to geographically isolated or underserved areas.

Conclusion

Store-and-forward teledermatology using mobile phones for management of patients in a rural primary healthcare centre, free clinic setting, is feasible. In this study, mobile teledermatology was not inferior to FTF consultation. There were no significant differences in clinical outcomes of patients who underwent FTF dermatologic consultation compared to those who underwent mdermatology consultations. The diagnostic concordances between the GP and the dermatology consultant differed between mdermatology and FTF groups, but management concordances were similar. Mobile camera phones are promising instruments in the delivery of dermatological services to rural health centres.

Future teledermatology studies should be conducted over a longer time period and should include patients consulting at any time in the rural health unit. This would more accurately simulate the real-life application of mdermatology. An extensive cost analysis should also be undertaken to determine the economic feasibility of an mdermatology service.

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Conflict of Interest. The authors declare no conflicts of interest.

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