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CLINICAL REPORT

Teledermatological Monitoring of Psoriasis Patients on Biologic Therapy

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Patients with psoriasis who are being treated with biologics require intensive monitoring. However, the monitoring tool teledermatology is not commonly used. We investigated the applicability of a mobile phone based teledermatological system for monitoring psoriasis patients on biologic therapy. Nineteen patients were given mobile phones with built-in cameras, in order to transmit health status data and images (mobile visits) weekly for a 6-month period. Face-to-face visits were carried out at weeks 0, 4, 12 and 24. Image quality, the Psoriasis Area and Severity Index (PASI), the handling of adverse events, and patients' feedback questionnaires were evaluated. Ninety-five percent of the images were of sufficient quality to enable accurate assessment of the PASI. The distance between the interpolated face-to-face PASIs and the corresponding mobile visit PASIs was 0.46 ± 2.15 (median ± interquartile range). All 155 adverse events were handled correctly by the system. This teledermatological system represents a reliable tool for management of psoriasis patients who are on systemic treatment. ***Key words: psoriasis; dermatology; biologics; telemedicine; eHealth.***

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Psoriasis is a common, chronic, inflammatory skin disease that displays a variable morphology, severity and course. According to population-based studies, 1–3% of the European population is affected by psoriasis (1–4).

Approximately 17–25% of patients with psoriasis have moderate-to-severe psoriasis, as shown by Meier & Sheth (5). Due to the chronic nature of the disease (and frequently occurring relapses) patients often require long-term systemic treatment. Traditional systemic therapies, such as photochemotherapy, fumaric acids, methotrexate, cyclosporin A and retinoids, show various and frequent side-effects and require intensive and continuous monitoring. Biologics, new agents targeting key steps in the inflammatory pathway of psoriasis, appear to have a favourable risk:benefit ratio (6). However, as for all new drugs that target the immune system, close monitoring is recommended (7). The regular check-ups necessary in patients on systemic treatment are time-consuming and cost-intensive and add to the burden of the disease; psoriasis patients are among those who experience the highest deterioration in their quality of life (8).

Previous studies have shown that the average patient's compliance with psoriasis therapy is approximately 60% (9–12). There are several reasons for discontinuing therapy, including medical reasons (e.g. insufficient response to treatment, adverse events and medication side-effects) and personal reasons (e.g. business and financial problems, forgetfulness, issues in the relationship between physician and patient, fear of deleterious side-effects, family problems or general lack of motivation).

Therefore the pivotal questions arise as to how to optimize compliance with therapy, and which system could be used to improve the monitoring of psoriasis patients who are on long-term systemic treatment.

Eminović et al. (13) assessed teledermatology as a promising technology to achieve these goals. In the past, this method has been used successfully for the early detection and diagnosis of skin cancer and for wound care management of patients with chronic leg ulcers (14–21). A pilot study conducted in our department by Frühauf et al. (22) indicated that this method might be a useful tool for monitoring the course of psoriasis.

The aim of this study was to devise an efficient and easy-to-use teledermatological monitoring system to record the course of the disease in psoriasis patients on a biologic agent, during both active episodes and remission phases, and to use this system for the early detection of adverse events. This should help to optimize therapy, intensify the patient-physician relationship, and improve compliance.

MATERIALS AND METHODS

Study design

Patients with psoriasis were recruited prospectively from the Department of Dermatology, Medical University of Graz, Austria, from March 2008 to February 2009. Inclusion criteria were: age 18–75 years; moderate-to-severe psoriasis for at least 6 months; eligible for treatment with a biologic according to the German S3-guidelines by Weisenseel et al. (23). A total of 20 patients were selected for inclusion and to receive treatment with a biologic agent. For consistency of study cohort, efalizumab was chosen as the first biologic treatment for all patients,

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with the possibility of changing to other treatments/biologics in case of adverse reactions or lack of response. Patients who had started efalizumab treatment before the study began were also eligible for inclusion.

The study was approved by the local ethics committee according to the Declaration of Helsinki. All subjects gave informed consent prior to the study.

Study setting and technical equipment

Each patient was given a mobile phone (Sony Ericsson K770i or K800i, London, UK) with a 3.2 megapixel camera that could be activated via a Java 2 Micro Edition (J2ME, Sun Microsystems, Inc., Santa Clara, CA 95054, USA) application.

Specific J2ME telemonitoring software was installed on the mobile phones in order to guide the patients through the process of data acquisition. Patients were instructed to log in by typing a PIN code whenever the software was started. They were then asked whether any adverse effects had occurred since the last transmission. For each region monitored a screen indicating the region was then shown, and the mobile phone's camera was started automatically. For each lesion additional information, such as whether the size of the lesion changed, could be entered. Finally, all data were encrypted, stored on the mobile phone, and data transfer to the monitoring centre was initiated via hypertext transfer protocol secure (https). If the data transfer was successful, all data were deleted from the mobile phone. In the event of transmission problems, the data were stored and could be transmitted later.

At the start of the study (week 0) each psoriasis patient was given detailed instructions and a training lesson over approximately 30 min on the appropriate use of the mobile device. During the 6-month period 4 face-to-face visits were conducted at our outpatient department. According to the study protocol these visits were performed at the start of the study (week 0), as well as at weeks 4, 12 and 24, including the necessary laboratory tests. The laboratory test at week 8 was performed by the patient's general practitioner. Mobile visits were carried out weekly over the whole study period at the patients' normal residence.

Mobile visit

Once a week, 2–3 days before the injection of the biologic, the patients were asked yes/no questions regarding their health (fever, night sweat, cough, tiredness, "feeling healthy") via their mobile devices and had the opportunity to provide additional information and comments.

In addition, patients reported on their body weight and quality of life. Patients also had the option of indicating their current body temperature and applying the Self Administered Psoriasis Area and Severity Index (SAPASI) as defined by Fleischer et al. (24). Finally, patients stated whether they had injected the biologic in the previous week.

Thereafter, the patients were asked to take photographs with the mobile phone camera of up to 5 predefined body regions that were affected by psoriasis.

Reference markers of defined size and colours were placed close to the lesions, in order: (*i*) to help the physician analyse the lesions; (*ii*) to help the patient evaluate the picture quality; and (*iii*) theoretically, to allow for automated size and colour correction (although this was not implemented). For each lesion, the patients were asked whether they had been assisted in taking the photograph, if the lesion had increased or decreased in size since the last recording, and if the infiltration had changed.

The physician examined the data transmitted by the patient via a web-browser and sent a feedback message via a secure protocol using a combination of short message service (SMS) and https (Fig. 1). In the event of a patient reporting adverse events or complications the physician was informed separately via the system. Hence, the physician was able to return a case-by-case specified feedback or, if necessary, to contact the patient by phone.

The data retrieval, transmission and method of analysis, including the system configuration and security settings of the mobile device, have been described previously (25).

Analysis methods

Six months after the end of the study all images collected were evaluated independently by four observers for image quality and specific features (erythema, infiltration, scaling) of the PASI. All of the observers were experts with experience in PASI assessment. One of the 4 observers (SK) cared for the patients for the course of the study and assessed the PASI at the face-to-face visits (henceforth referred to as "life"-PASI); the remaining 3 observers were independent clinical dermatologists and were not involved in the study patient care.

For a blinded evaluation the whole set of images was mixed up and single images (Fig. 2) were shown on a computer screen one by one. In a first step, the image quality of the whole set of images was assessed as "good", "sufficient" or "insufficient" by each observer. Images with insufficient quality were divided into "blurred", "lacking brightness" or "other deficiencies".

In a second step, all images that were assessed as "good" or "sufficient", were evaluated regarding specific features of the PASI (erythema, infiltration, scaling). In order to calculate the PASI, the size of the affected area was retrieved from the prior face-to-face visits. Furthermore, for body regions where no picture was taken all PASI features (erythema, infiltration, scaling, area) determined at the previous face-to-face visits were used. These components were utilized to calculate a PASI (henceforth referred to as "tele"-PASI). This evaluation was done without knowledge of the "life"-PASI.

Finally, the obtained "tele"-PASIs (usually available for each week of the study) were compared with the "life"-PASIs from the face-to-face visits (available for weeks 0, 4, 12 and 24). Therefore, the first two "life"-PASIs (weeks 0 and 4) were taken and a line was interpolated between these two values (blue lines in Figs 3 and 4). For each "tele"-PASI obtained between weeks 0 and 4, the distance of the "tele"-PASI to the time-wise corresponding interpolated "life"-PASI was calculated (i.e. vertical distance between the "tele"-PASI and the blue lines in Figs 3 and 4). Similarly, the "life"-PASI was interpolated between weeks 4

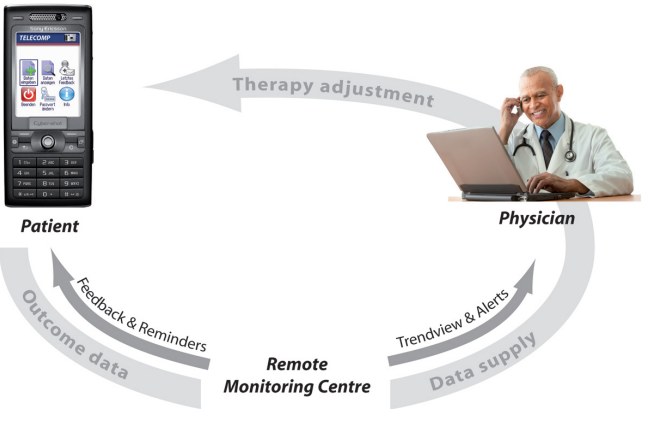

Fig. 1. The teledermatological monitoring system. Data are acquired by the patient using a mobile phone and sent to the Remote Monitoring Centre at the Austrian Institute of Technology. The physician can assess this data via a web-browser and send a feedback message.

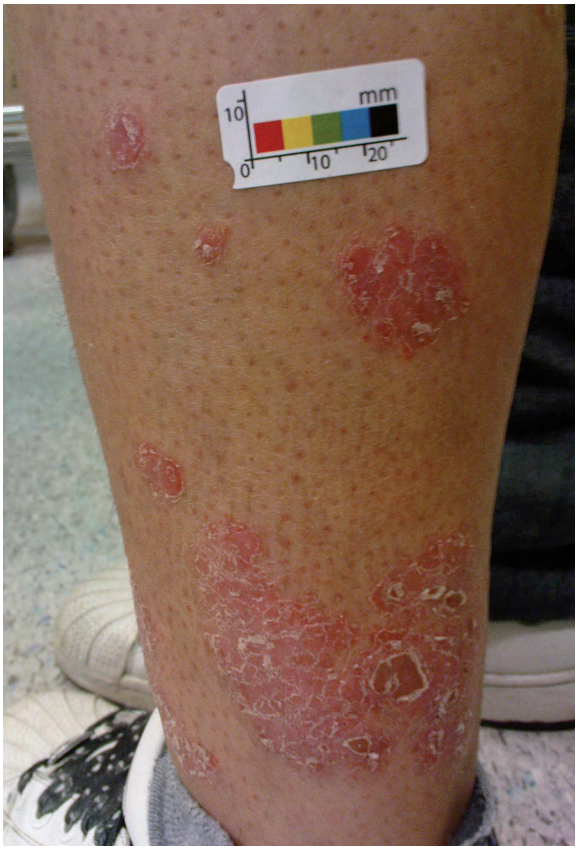

Fig. 2. Example of a digital image (patient number 4, week 1).

and 12, as well as between weeks 12 and 24, and the respective "tele"-PASIs were compared with these interpolations.

After study termination each patient received a feedback questionnaire including 20 questions regarding handling of the mobile device, required time for taking images, entering and submitting data, future demand for such a teledermatological system in routine use, and personal opinion about the system.

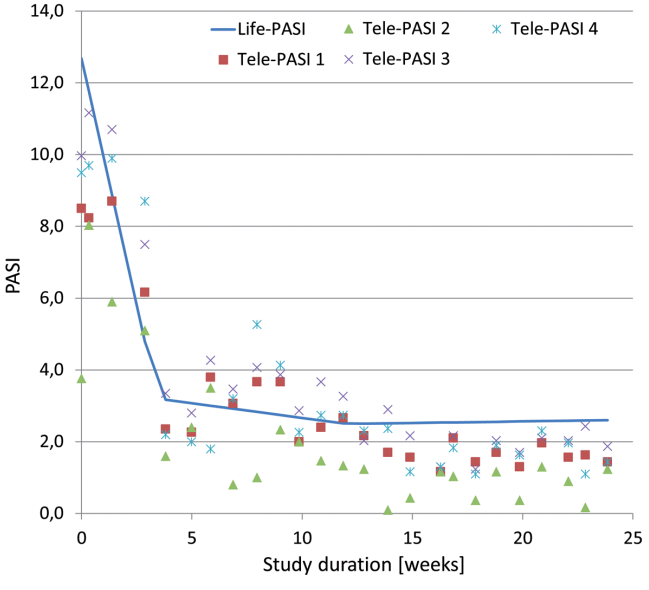

Fig. 3. Example 1 for comparison of "life"- and "tele"-PASIs (patient number 2). Results from all four observers (Tele-PASI 1, 2, 3, 4).

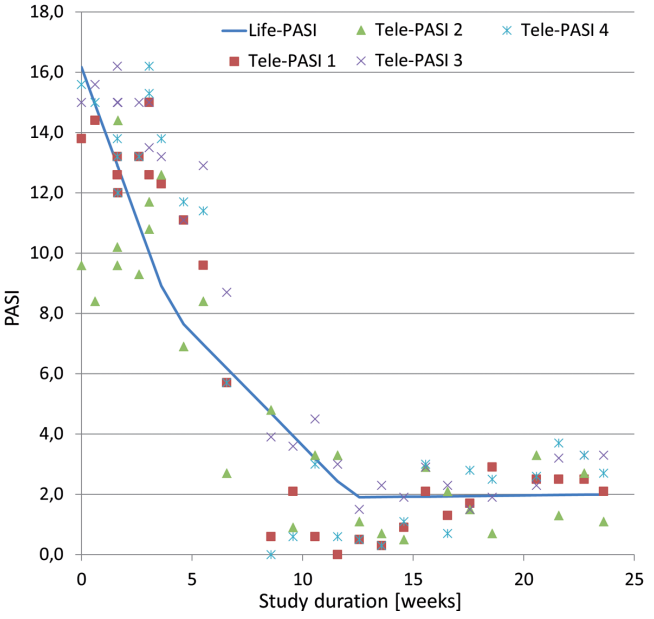

Fig. 4. Example 2 for comparison of "life"- and "tele"-PASIs (patient number 7). Results from all four observers (Tele-PASI 1, 2, 3, 4).

RESULTS

General observations

Overall, 19 patients (12 males, 7 females; mean age ± standard deviation (SD) 46.16 ± 12.71 years) with moderate to severe plaque psoriasis were included in the study.

The median PASI at the start of the study was 10.31 ± 6.27 (± interquartile range (IQR)). Ultimately, 15 of the 19 patients finished the whole study period of 6 months. Three patients dropped out of the study after month 3, one due to elevated liver enzymes (collected at laboratory test week 12), one due to physical unavailability, and one due to treatment failure. In the case of "treatment failure" the lack of response to treatment was already suspected by observing the weekly sent images. However, according to local guidelines, the decision to change the treatment was made at the week 12 visit. In one case the study had to be discontinued after the first injection of efalizumab due to aseptic meningitis.

Treatment with the biologic efalizumab was either initiated at the beginning of the study (14 patients) or the patients were already being treated with efalizumab (5 patients). Efalizumab was administered subcutaneously every 7 days according to the standard protocol.

In February 2009, the European Medicines Agency recommended suspending efalizumab from sale in the European Union (6, 7, 26). Hence, a planned twentieth patient could not be included and the medical treatment of the remaining patients had to be changed to other treatment modalities. However, the withdrawal of efalizumab did not have any major impact on our study, as the main focus of the study was on the applicability of our teledermatologic system.

Altogether, 9 patients remained on efalizumab throughout the whole study period of 6 months, whereas in 6 patients the treatment was changed to other modalities (5 patients changed to etanercept and 1 to fumaric acids).

Data analysis

A total of 1,112 images was sent by all 19 patients via their mobile devices during 338 mobile visits.

Compliance with the teledermatological monitoring procedure (calculated as a percentage of the data sent by the patients within 3–9 days after their last transmission) among the 15 patients who finished the study was 76.7 ± 19.9%.

Overall, 293 feedbacks (16.28 ± 5.68 per patient) were provided to the patients. The difference between the number of mobile visits and the number of feedbacks sent (338 vs. 293) can be explained as follows: (*i*) data transmission problems occurred 27 times, and the data entered by the patient were stored intermediately on the mobile phone (e.g. due to network coverage). Data transmission was then carried out in the course of the subsequent mobile visit, together with the data for the subsequent visit, and, therefore, no separate feedback was given for the previous mobile visit; (*ii*) in seven cases the patient had a face-to-face visit shortly after transmitting data (within 1 day) and no adverse event was reported; (*iii*) feedback transmission problems occurred 7 times at the beginning of our study; (*iv*) in 4 cases new data were submitted by the patients within less than 2 days and a single feedback for both mobile visits was created afterwards.

On average, the time from receiving the patient's data to sending a feedback message was 1.29 ± 1.27 days. These time periods did not significantly differ between "normal" feedbacks (1.27 ± 1.27 days) and feedbacks after reported adverse events (1.32 ± 1.27 days).

Efficacy

A total of 1,057/1,112 images (95.05%) were classified as of "good" or "sufficient" quality by at least two of the four dermatologists. In detail, 560/1,112 images (50.36%) were of good quality and 497 images (44.69%) were of sufficient quality for the teledermatological evaluation of psoriasis lesions. The remaining 55/1,112 images (4.95%) were of insufficient image quality: 48 images were blurred and 7 images lacked brightness.

When comparing "life"- and "tele"-PASIs the median distance between the interpolated "life"-PASIs and the time-wise corresponding "tele"-PASIs was 0.46 ± 2.15 (median ± IQR) (Figs 3 and 4). Regarding the single PASI features (erythema, infiltration, scaling) the median distances were: erythema 0.63 ± 0.47, infiltration 0.75 ± 0.50, and scaling 0.61 ± 0.36. The outcome of the PASI comparison was not influenced by the image quality ("good" or "sufficient").

Safety

In total, 155 adverse events (5.63 ± 5.16 per patient) were reported by the patients during the whole study period. In detail, not "feeling healthy "was reported 31 times, fever 5 times, night sweat 25 times, cough 39 times, and tiredness 55 times (Table I). All adverse events that occurred were covered by the five yes/no questions regarding the patients' health conditions, and no additional comments were necessary to report adverse events properly.

In case of reported fever (3.22% of 155 adverse events), the patient was additionally contacted by phone to ensure that the treatment was paused. In 7 cases (6.80% of 103 adverse events excluding double entries) a phone call was necessary to gather more information about the patient's state of health to decide whether he or she should continue with the biologic treatment. However, all adverse events could be handled solely via feedback message (SMS and https) or with an additional phone call.

The only serious adverse event occurring in our study was an aseptic meningitis: after the first injection of efalizumab the patient reported fever and headache by phone call. The patient was seen immediately in our outpatient department, hospitalized, and recovered completely after 10 days.

Feedback questionnaire

Overall, 17 feedback questionnaires were returned by the patients for evaluation. Sixteen out of 17 patients (94.1%) experienced no problems with taking images

Table I. *Adverse events occurring during the study (338 mobile visits, 103 visits with one or more adverse events)*

Adverse events	*n* (%)	Patients reporting adverse event, *n*	Feedback, *n*		Medication pauses, *n*
			SMS	Phone call	
Tiredness	55 (35.48)	11	53	6	2
Cough	39 (25.16)	10	38	7	1
Not feeling healthy	31 (20.00)	11	31	4	6
Night sweat	25 (16.13)	6	25	4	1
Fever	5 (3.23)	4	5	5	5
Total	155	19	101	7	7

SMS: short message service.

or with entering the data. During the study period, one patient living in a remote area encountered data transmission difficulty several times due to insufficient network coverage. The median of the time periods of the whole process (taking images, entering and submitting data) was 5 min (mean time period 6.76 min).

Twelve of the 17 patients (70.6%) stated that they would use their own mobile phones for this monitoring procedure in the future. Of the remaining five patients, two assessed their mobile phone as not applicable for this procedure and one patient judged the data transmission process to be too expensive. Two patients gave no further explanations.

Fifteen of 17 patients (88.2%) assessed the teledermatological system as a "very good idea", while two regarded it as a "good idea". Furthermore, 16/17 patients (94.1%) stated that they would recommend this service to other psoriasis patients, while one patient stated that it was likely that he would do so.

DISCUSSION

To date, no teledermatological system for continuous monitoring of psoriasis patients is in routine use, although its advantages are evident.

The system described here focuses on optimizing the therapy with a biologic by improving the communication between patients and physicians in order to intensify the patient–physician relationship and to improve patients' compliance. This method can also be seen as a compliance motivating tool that aims to strengthen the responsibility of the individual patient and facilitate the patient–physician interaction. In our daily experience, some patients, even if instructed in detail, do not contact their physician when adverse events occur, and continue to administer their medication. In these cases, reporting of adverse events is delayed to the subsequent visit, sometimes weeks later. To overcome this problem, transmission of data was carried out weekly, although monthly transmission of images would be sufficient for the teledermatological evaluation of psoriasis lesions.

The image quality, a key point for the adequate assessment of the psoriasis plaques, was of good or sufficient quality in 95.05% of the sent images. Hence, the physician could properly assess and evaluate the course of the skin lesions. The insufficient quality of the majority of the unusable images was caused either by a lack of experience in handling the mobile phones' camera or by insufficient light. In most cases the image quality could easily be improved after giving further technical advice to the patient via SMS and https.

On average, the obtained "tele"-PASIs and the corresponding "life"-PASIs from the face-to-face visits showed no considerable difference (0.46 ± 2.15). This result indicates that the evaluation of teledermatologically acquired images is a reliable substitute for a face-to-face assessment. However, a certain amount of the found covariation could be explained by the fact that the same size area, inferred from the face-to-face visits, was used for both the "life"- and the "tele"-PASIs.

Regarding the different features of the PASI (erythema, infiltration, scaling), infiltration was, as expected, the most difficult aspect to evaluate, due to the two-dimensionality of the images. The infiltration was estimated based on the digital image and daily practical experience.

Using this system we were able comprehensively to gather information about and correctly handle all of the 155 adverse events that occurred, via feedback message or an additional phone call alone. The only serious adverse event occurring in our study was also dealt with properly via the system. Therefore, this system appears to represent a proper tool for management of psoriasis patients who are on systemic treatment, as no relevant data were lost in our study and all adverse events were dealt in a timely manner.

Due to the time-saving characteristics and rapid responsiveness of this system, it was well accepted and patients felt well cared for. As a result the patient–physician relationship intensified, the patients' compliance was enhanced (79% in our study vs. 60% reported in previous studies) and the patients' satisfaction level was high. Overall, 88.2% of patients assessed this teledermatological system as a "very good idea", while the remainder (11.8%) assessed it as a "good idea". Furthermore, 94.1% of patients stated that they would recommend this service to other psoriasis patients, while one patient stated that he/she would be likely to do so. This supports the positive perception of the concept by patients.

Based on current technology, the system can be used easily with up-to-date mobile phones that have a high-resolution camera. Additionally, the operational costs of this system, which are mainly system operation and data transfer charges, are relatively low in comparison with operational costs associated with face-to-face visits (e.g. the costs of patients' transport).

In the future, such a telemonitoring system could help to reduce the number of face-to-face visits, as the required laboratory controls/results could also be transmitted and reviewed via teledermatology, and physical examinations could be carried out by the general practitioner close to the patient's home.

Although efalizumab was chosen as the initial biologic agent in the study, this teledermatological system could also be used for monitoring other systemic treatments. Further investigations with a larger study population are required in order to validate the findings of this study.

The results indicate that the teledermatological system described here is a promising and reliable tool for the

long-term management of psoriasis patients on systemic treatment (e.g. biologics). The course of the disease can be properly monitored, side-effects of the medications used and adverse events can be detected earlier, and a timely response to disease worsening is possible. The system is easy to use and allows the patient to stay in close contact with the attending physician. These advantages mean that the system is well accepted by the patients. Furthermore, this tool empowers the patients in their personal responsibility. This teledermatological monitoring system could be used to reduce the number of face-to-face visits required.

The authors declare no conflicts of interest.

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