Color-coded etiological keys: A simple survey tool towards amputation-free limb survival in diabetic foot lesions

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ABSTRACT
Aims/Introduction: We devised a simple implementable color-coded etiological key survey based on six significant categories to screen and manage all diabetic foot patients. The study results were analyzed to verify the impact of this survey.

Materials and Methods: First we carried out a retrospective internal survey of all diabetic patients that presented to us during the period from January 2004 to January 2007. We used this analysis to develop the color-coded etiological survey, and applied it to analyze patients prospectively for 5 years from May 2007 to May 2012. Out of 4,102 diabetic foot patients, 739 patients were referred by other medical facilities for major amputation as a result of the severity of their foot lesions. This group was then subjected to further analysis to study the value and impact of the survey on amputation-free limb survival.

Results: Blood quality abnormalities were most prevalent followed by peripheral occlusive diseases, whereas tissue loss was the least. After the completion of the assessment process, management was implemented according to the defined protocol based on the lesions’ characteristics. The primary end-point of major amputation-free limb survival was achieved in 72.5% of patients, with an average hospital stay of 13.3 days. Statistical analysis of the etiological keys showed a significant impact of tissue loss, and previous foot surgery as a poor predictor of limb loss.

Conclusion: We conclude that the implementation of the color-coded etiological key survey can provide efficient and effective service to diabetic foot victims with comparable outcomes to dedicated diabetic foot clinics.

INTRODUCTION
Diabetes is a growing global epidemic, with almost 300 million people predicted to be affected by 2025. Presently, Egypt is in the ninth place in diabetes prevalence, and is expected to rise to the seventh place by 2030. Diabetic foot lesions are the most common cause for hospital admission among diabetics, and it is estimated that at least 15% of all diabetics will experience one form of diabetic foot lesion at least once in their lifetime. Approximately 85% of all non-traumatic amputations occur in diabetics, and at least 80% of those are preceded by active foot lesions.

Although it is well understood that the medical teams designated for diabetic foot care would benefit the patient, their advantages in preventing amputation are abundantly clear. Rogers described how an organized program can reduce the amputation rate by 72% over 1 year in a county hospital. The lack of an organized team dedicated to diabetic foot care aided by the narrow scope of specialty-oriented rather than problem-oriented solving strategies often increases the possibility of missing an integral etiological problem. This eventually results in limb loss and major amputations.

The Cairo University Hospitals, with over 3000-bed capacity, are considered as tertiary referral centers for almost all medical specialties, including vascular surgery services where diabetic foot problems constitute at least 37% of the workload.
Almost 50% of our diabetic patients are referred from other medical facilities for a second opinion regarding their foot and/or limb problems. A considerable number of those patients are suggested for major amputation as a result of their profound foot problems.

Driven by this large number of diabetic patients, referred to us with foot problems, suggested for major amputation, we carried out a retrospective internal survey for all diabetic patients presented to us during the period between January 2003 to January 2007.

During these 3 years, we received a total of 3,152 patients, out of which 487 patients were suggested by other medical facilities for major amputation. Of these, just 421 patients had complete records available for analysis.

We could define certain modifiable etiological risk factors (Table 1). Other non-modifiable risk factors included female sex, age older than 63 years and duration of diabetes more than 9 years.

In order to verify the impact of etiological factors-targeted treatment on amputation-free limb survival, we devised a simple color-coded etiological key survey to emphasize the problem-oriented rather than the specialty-oriented diabetic foot management protocol.

We grouped the significant modifiable etiological factors into six main categories, where each category was given a distinct color tag to be posted on the first page of the patient’s file (Table 2).

The blood quality as an etiological factor was considered significant when hemoglobin level was below 9 g/dL and/or serum albumin was below 3 g/dL. While the absence of pedal pulses, and ankle brachial index measuring below 0.9 or ankle peak systolic velocity below 75 cm/s indicated significant blood quantity factors. Some of the patients enlisted in our study group did not show critical limb ischemia (CLI), but their ischemic potential was still considered significant in regard to their foot lesion healing.

Associated comorbidities were either systemic or regional conditions that we thought would impair the healing process or affect the quality and modality of the intended intervention. This included systemic diseases, such as heart failure (congestive or ischemic), chronic renal failure, and collagen diseases with immune vasculitis such as rheumatoid arthritis, systemic lupus, scleroderma and non-specific arteritis. Regional diseases included limb conditions, such as chronic lymphoedema and chronic venous insufficiency.

We defined foot bone lesions for all patients suffering from foot bone deformities, Charcot’s neuroarthropathy or radiologically-evident fracture, dislocations and/or osteomyelitis. Any surgical intervention aimed at treatment of the foot lesion in question, according to the patient’s history and previous investigations, that was improperly carried out as a result of the missing management of other etiological factors, was considered under the previous surgery group. Any tissue loss because of gangrene or necrotizing infection that resulted in impairment of the physiological weight-bearing function of the foot was considered significant for tissue loss factor.

The survey was applied to all patients with diabetic foot problems. However, those patients who were suggested for major limb amputation by other medical facilities were subjected to further analysis for examining the impact of this targeted approach in amputation-free limb survival.

## MATERIALS AND METHODS

First, we carried out a retrospective internal survey of all diabetic patients who presented to Cairo University Hospital, Cairo, Egypt, during the period from January 2004 to January 2007. We used this analysis to develop the color-coded etiological survey, and applied it to outline the patients’ management strategy prospectively from May 2007 to May 2012. All patients with diabetic foot lesions were prospectively screened according to our devised survey protocol in the Vascular Surgery Department at Cairo University Hospitals.

During their first visit at the outpatient department, each patient was evaluated by the chief resident, and a series of investigations was requested according to the patient’s presentations (Table 3).

> After the investigations, the patient was asked to attend a second follow-up visit, where an attending physician would re-examine and review the results of the requested investigations.

### Table 1 | Pre-study significant factors

| Pre-study significant factors |
|------------------------------|
| 1 Anemia Hb <9 g/dL |
| 2 Hypoalbuminimia <3 g/dL |
| 3 Abnormal albumin/prealbumin ratio |
| 4 Peripheral arterial disease |
| 5 Bone deformity |
| 6 Osteomyelitis |
| 7 Charcot joint |
| 8 Chronic liver impairment |
| 9 Coronary artery disease |
| 10 Obstructive airway diseases |
| 11 Collagen diseases |
| 12 Autoimmune vasculitis |
| 13 Previous foot surgery |

### Table 2 | Six etiological key factors

| Etiological key factors |
|-------------------------|
| 1 Blood quality |
| 2 Blood quantity |
| 3 Associated comorbidities |
| 4 Bone lesions |
| 5 Previous foot surgery |
| 6 Tissue loss |

*Table 2: Six etiological key factors*
Then, in accordance with our color-coded etiological key survey (Figure 1), a distinct color code tag(s) (were) posted on the cover page of the patient’s file.

After this labeling and tagging, the clinic’s registered nurse and medical secretary were required to reserve other specialty’s appointments in accordance with the color tags posted on the patient’s file.

Furthermore, our patients were given priority in appointment booking according to the color tags. In this way, the patients could have more than one appointment/day. Moreover, the registered nurse was required to finish this round-up of other specialty visits within a maximum of five working days. All consultation documents and proposed management plans were recorded and well-documented in the patients’ file.

In the pre-admission visit, the patient’s investigations, consultation’s reply and surveys were reviewed by a senior vascular surgery registrar/attending consultant. Their job is to orchestrate the management steps in a chronological manner, and set the milestones for the patient’s in-hospital management before admission (Figure 2).

The devised flow chart protocol was designated to all the patients with profound foot lesions, as well as to the patients suffering from any diabetic foot problems. Yet those who were suggested for major amputation were the subject of the present report analysis.

On some occasions where the patient’s condition mandates immediate hospital admission and urgent intervention, such as in the case of sepsis, spreading gangrene, diabetic ketoacidosis and so on, our strategy differs. The initial management steps shift to control the patient’s acute illness first and then follow the aforementioned steps while admitting the patient.

All the patients’ data, pre-hospital management, period of hospital stay, number of specialties concerned, number of interventions, and the total time taken for the final results were recorded and tabulated.

### RESULTS

During the study period, we received 4,102 diabetic patients with foot lesions. Of these, 739 patients were initially referred from other medical facilities for major limb amputation; those patients were subjected to further analysis in the present study.

The patients’ average age was 52 ± 6.3 years, with a range of 41–69 years. Of them, 522 (79%) were male patients. The duration of known diabetes ranged 9.5–21 years, with an average of 11 ± 2.3 years.

On implementation of our color-coded etiological key survey, blood quality abnormalities were found in 486 (66%) patients, whereas tissue loss was found in 59 (8%) patients (Figure 3).

Anemia and hypoalbuminemia were the most commonly encountered blood quality abnormalities (84.6%), whereas other abnormalities included disturbed serum electrolytes (10.3%) and abnormal liver function testing (7.8%).

Significant occlusive arterial diseases were observed in 310 (41.9%) limbs. Femoropopliteal occlusions were found to be the most common, occurring in 198 (63.8%) limbs.

Hypertension, chronic renal impairment and ischemic heart diseases represented the most frequent medical comorbidities. However, a considerable number of our patients had suffered collagen diseases, such as rheumatoid arthritis, systemic lupus and scleroderma (7%).

Foot bone deformities and diabetic Charcot joint were the most common bone problems encountered in our population (53.5%), followed by osteomyelitis (25%).

Incision, drainage and debridement constituted the majority of previously carried out foot procedures, whereas gangrenous patch/toe(s) and neuropathic ulcers were the most frequent forms of tissue loss.

The average time from initial presentation to hospitalization was 7 ± 2.1 days (range 4–13 days), whereas hospital stay ranged 5–28 days with an average of 13 ± 3.3 days. The average number of interventional/surgical procedures carried out per patient was 2.3 ± 0.2, with the range of one to four procedures per patient. The number of specialists involved ranged from one to four, with an average of 3.1 ± 0.2.

Balloon angioplasty with selective stenting was our prime revascularization modality (284/310 limbs) with initial clinical

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**Table 3** | Basic initial investigations

| Laboratory investigations | Complete blood count |
|--------------------------|----------------------|
| ESR-CRP                  |                      |
| Serum urea               |                      |
| Serum creatinine         |                      |
| Serum albumin & prealbumin |                  |
| Serum bilirubin          |                      |
| Hemoglobin A1C           |                      |
| Two-views digital foot X-ray |          |
| Arterial duplex (impalpable pulse) |  |
| Chest X-ray and ECG      |                      |

CRP, C-reactive protein; ECG, electrocardiogram; ESR, erythrocyte sedimentation rate.
success of 87%, whereas other revascularization procedures, including femoropopliteal bypass and femorodistal bypass, represented the remaining treatment modality carried out with initial clinical success of 84%. Unfortunately, major limb loss was eventually required in some cases, despite successful revascularization as a result of the severity of associated infection and/or tissue loss.

Bone resection and minor amputation were the most practiced bone surgeries in our population, whereas joint arthrodesis and deformity correction represented the rest of the orthopedic procedures carried out.

Healing of foot lesions (for those who survived major amputation) occurred in 46 ± 9.3 days (range 21–128 days).

The overall rate of amputation-free limb survival was 72.5% (536 limbs), in which minor amputation occurred in 154 limbs (21%) and major amputation occurred in 203 limbs (27.5%).

Statistical analysis of the color-coded etiological keys against the primary outcome for amputation-free limb survival was carried out using one-tailed Fisher’s exact probability testing and one- and two-tailed Student’s t-test probability testing. The results showed a significant impact on the amputation for tissue loss \( (P = 0.022) \) and previous foot surgery \( (P = 0.031) \) and, to a lesser extent, bone lesions \( (P = 0.045) \) and associated comorbidity diseases (Tables 4,5).

**DISCUSSION**

According to the 1999 American Diabetes Association Consensus Statement on diabetic foot ulcers, “it is generally believed that foot ulcer in diabetics becomes a chronic wound due to numerous comorbidities that include, yet are not limited to, biomechanics, vascular insufficiency, diminished protective sensation, renal disease and altered nutritional status”\(^6\).

The multiplicity of the causative parameters for both chronicity and severity of diabetic foot lesions presents a continuous call for teamwork designated for diabetic foot care\(^19\). A
Table 5 | One-tailed and two-tailed statistical analysis

|                | Total (n) | AFLS | Major amputation | Fisher’s exact test one-tailed | Student’s t-test one-tailed | Student’s t-test two-tailed |
|----------------|-----------|------|------------------|-------------------------------|----------------------------|----------------------------|
| Blood quality  | 486       | 401  | 85               | 0.757503                      | 0.221386                   | 0.442771                   |
| Blood quantity | 310       | 251  | 59               | 0.380831                      | 0.087447                   | 0.174893                   |
| Associated diseases | 207 | 173  | 34               | 0.205823                      | 0.048988*                  | 0.097977                   |
| Bone lesions   | 203       | 131  | 72               | 0.111027                      | 0.04517*                   | 0.090341                   |
| Previous foot surgery | 132 | 63   | 69               | 0.03912*                      | 0.031167*                  | 0.062335                   |
| Tissue loss    | 59        | 38   | 21               | 0.009847*                     | 0.022184*                  | 0.044368*                  |

*Significant P-value. AFLS, amputation-free limb survival.

dedicated diabetic foot care team often requires certain logistics that might not be available in most hospitals; for example, dedicated clinics, personnel and budget allowances.

Therefore, in the absence of such dedicated teams, the patients’ care is often shifted to specialty-oriented rather than problem-oriented practice. This can result in the possibility of missing an important etiological factor for the patient’s foot lesions, and hence, can endanger limb survival.

Thus, we devised our simple implementable color-coded etiological key survey that allowed us to carry out a problem-oriented approach within the setting of the usual clinic workload without the need for dedicated time and place. Furthermore, apart from the designated registered nurse and medical secretary, no other dedicated personnel were required.

Our overall amputation-free limb survival rate approaches that of the other published data from designated diabetic foot clinics. This was achieved in accordance with the reduced pre-hospital and hospital stay period. We believe that this was due to the compensation for consultation time loss and pre-planning dilemma that often results in the longer time spent between clinics and requested investigations.

As shown by the statistical analysis, patients who had a history of tissue loss and/or previous foot surgery and bone lesions had the least chance of amputation-free limb survival. In other words, peripheral arterial diseases and correctable blood quality had the best chance of limb survival.

CLI represented a good share in our population with almost 42%. With the advances in endovascular therapies, we could achieve remarkable results with its positive impact on limb salvage. However, some cases still had to be amputated because of other compelling factors; for example, sepsis. Statistically, the presence of peripheral arterial diseases had a significant impact on the amputation-free limb survival.

CLI and, in particular diabetic foot, are still considered to be the most consistent workload in our department, while the prevalence of amputations oscillates from 0.2 to 4.8%. Diabetes is the most important risk factor for CLI, and it is well-recognized that diabetic patients have a high risk of both amputation and death compared with non-diabetics.

Complications associated with diabetes are difficult to manage, and require a significant commitment in terms of healthcare. Prompers et al. reported that the presence of CLI greatly increases the risk of major amputation. They reported that the presence of diabetic neuropathy (even motor or sensory) is linked only to a higher incidence of ulceration; no major risk of amputation was detected.

Early control of the infective process represents the main therapeutic goal of emergency surgery in infected diabetic foot. Despite the benefits of pharmacological therapy, arterial revascularization remains a mainstay in the management of CLI, as the restoration of adequate blood flow to the foot is crucial to provide pain relief, promote wound healing and avoid amputation. Both percutaneous transluminal angioplasty and open arterial reconstruction are feasible and safe in this setting. Recently, more aggressive endovascular techniques have been developed to improve the results in vessels below the knee. Techniques, such as subintimal angioplasty, retrograde approach with transpedal access, subintimal arterial glossing with antegrade-retrograde intervention, transcollateral angioplasty and pedal-plantar loop, are improving the success rates of percutaneous transluminal angioplasty, even in the most distal vascular territories.

Timing has a key role in the treatment of diabetic foot, especially if it is infected. Faglia et al. have confirmed how, in the case of CLI (especially if it is associated with a severe infection), an early surgical treatment of the infection, followed by early revascularization procedure, can achieve limb salvage or a more distal level of foot amputation. Caravaggi has proposed an “integrated surgical approach” that considers the main aspects of treatment of severe foot infection: time, emergency surgical treatment and revascularization procedures. As early surgical treatment of infection is closely correlated with limb salvage, surgical debridement must be carried out as soon as possible, regardless of the vascular condition of the foot. Revascularization procedures, both surgical or endovascular, are secondary in comparison with the local and systemic infections control.

In the absence of well-organized diabetic foot clinics with dedicated team members and logistics, the implementation of the color-coded etiological key survey can provide efficient treatment to diabetic foot victims.

The color-coded etiological key survey is economical, and poses no additional financial burden to hospital logistics and funds. Furthermore, it is a fast, reliable and an expeditious approach for complex diabetic foot problems.
We recommend that this color-coded etiological key survey should be added in the diabetic foot examination sheet. We also advocate that this survey should be used by all medical specialties dealing with diabetic foot problems, especially those hospitals that lack dedicated foot clinics.

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DISCLOSURE
The authors declare no conflict of interest.

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