ORIGINAL ARTICLE

The effects of topical anesthesia on outcomes and glucose control in diabetic patients treated with split-thickness skin graft surgery

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Abstract

Background: Using split-thickness skin grafting to treat diabetic foot and leg ulcers is common. Diabetic patients usually exhibit multiple comorbidities and high risks of adverse responses to general and spinal anesthesia. Topical anesthesia can be an alternative to avoid these risks. In this study, the clinical experience of split-thickness skin grafting under topical anesthesia was demonstrated, to evaluate its effectiveness and benefits in diabetic patients.

Methods: From 2018 to 2020, diabetic patients with foot or leg wounds undergoing split-thickness skin grafting were reviewed and categorized into two groups according to the anesthesia methods: topical anesthesia and general/spinal anesthesia. Patient demographics, wound characteristics and healing status, postoperative complications, and perioperative blood glucose levels were recorded and analyzed.

Results: During the study period, 28 patients underwent split-thickness skin grafting under topical anesthesia and 46 under general/spinal anesthesia. The rate of complete wound healing in 4 weeks was similar in both the groups. The topical anesthesia group suffered fewer postoperative infections (3.6% vs 21.7%, $p = 0.044$), required shorter postoperative hospitalization (8.3 ± 6.2 vs 11.1 ± 7.2 days, $p = 0.048$), and exhibited lower mean blood glucose levels and less glucose variability than the general/spinal anesthesia group.

Conclusion: Conducting split-thickness skin grafting under topical anesthesia was shown to be a safe and effective means of treating leg and foot wounds in diabetic patients.

Keywords: Diabetic patients; Foot ulcers; Split-thickness skin graft; Topical anesthesia

1. INTRODUCTION

Diabetic foot wounds are complex and do not heal easily. They are the leading cause of hospitalization and limb amputations among diabetics. Timely healing and wound closure are critical to reducing the associated medical costs and morbidity.[1] Nowadays, there are many available wound care products and synthetic biomaterials, but split-thickness skin grafting (STSG) remains the gold standard and is a first-line treatment for lower extremity wounds associated with diabetes.[2]

In 2016, the Cochrane Review demonstrated skin grafting and tissue replacement to be a superior treatment for foot ulcers in people with diabetes.[3] Another meta-analysis published in 2019 showed that skin grafts increase the healing rate of diabetic foot and leg ulcers and found the rate of recurrence, infection, and need for regrafting to be relatively low.[4]

STSG is a common procedure in plastic and reconstructive surgery and is performed using different methods of anesthesia. However, diabetes is characterized by altered carbohydrate metabolism, leading to hyperglycemia and increased perioperative morbidity and mortality. Additionally, diabetic patients often have complex comorbidities that affect their hemodynamic and respiratory status under general anesthesia (GA) and spinal anesthesia (SA). This can be a challenge for anesthesiologists.

Although local anesthetics can avoid such risks, they do not eliminate procedural pain and multiple injections are required, particularly if the harvest area is large. This may be intolerable for the patient.

A topical anesthetic that utilizes a eutectic mixture of lidocaine and prilocaine (EMLA) can offer an alternative solution. In the late 1980s, several studies demonstrated the safety and effectiveness of harvesting STSG using TA.[5,6] Our group has previously conducted a randomized controlled trial to demonstrate that patients undergoing STSG surgery under TA had less early postoperative donor site pain and fewer adverse effects than those treated under GA.[7]

Previous reports have primarily focused on the effect of TA for STSG; however, there has been no research addressing

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patient selection for this procedure. In the present study, we assessed the variables that determine patient suitability for this procedure. As diabetic patients tend to have more preexisting comorbidities, including peripheral artery occlusive disease (PAOD), chronic kidney disease (CKD), and cardiovascular disease, which increase the risk of GA or SA, the presence of these conditions can be indicative of the need for an alternative form of anesthetic. Another indicator for suitability is neuropathy, which is sometimes comorbid with diabetes. This can render the patient less sensitive to wound pain and facilitate skin graft surgery under TA. Additionally, poor perioperative glucose control has been proven to be associated with postoperative infection.[8] We inferred that diabetic patients undergoing STSG under TA may have better postoperative glucose control because the precluded need for preoperative fasting allows them to follow regular glycemic control protocols.

The objective of this study was to evaluate the effectiveness and benefits of STSG surgery under TA with EMLA in diabetic patients with foot and leg wounds.

2. METHODS

This was a retrospective, non-randomized, single-center study. It was approved by the Research Ethics Review Committee of Far Eastern Memorial Hospital (protocol code 110295-E, date of approval: December 16, 2021). We collected and analyzed the clinical and surgical data of all diabetic patients treated at our institution from January 2018 to December 2020. Those with lower leg or foot full-thickness skin defects requiring skin graft reconstruction were enrolled and the operation notes and wound images were reviewed. In all patients, the wounds were confirmed to be granulating well without infection sign and suitable for an immediate skin graft. These patients underwent standard STSG surgery using different methods of anesthesia based on joint decisions between the surgeons and patients. The patients were separated into two groups: TA and GA/SA. Aside from the anesthesia method, the same protocols were followed in surgical procedures and postoperative care for both groups.

Exclusion criteria included being under 20-years-old, having a wound size >200 cm^2, use of a donor site other than the thigh, and complicated wounds requiring additional surgical procedures during the STSG surgery, such as toe amputation.

2.1. TA protocols

In the TA group, the generic drug eutectic mixture local anesthetic (EMLA; Lipry, Fuyuan, New Taipei City, Taiwan), containing lidocaine (25 mg/g) and prilocaine (25 mg/g), was used for anesthesia. The donor site was shaved and cleaned and a thick layer of EMLA (>1.5 g/10 cm^2) was applied evenly and covered with an occlusive plastic dressing. After 2–5 hours, the patient was taken to the operating room (OR) and the cream was removed before prepping and draping (Fig. 1).

2.2. STSG surgery

Skin graft surgery was performed using the conventional method. Harvesting was the first step of the surgery before debridement of the recipient site. The graft was harvested with a dermatome machine (Zimmer Biomet, Warsaw, IN, USA) preset to a thickness of 6–10/1000 inches. Pain intensity was evaluated and recorded using a visual analog scale (VAS) ranging from 0 (no pain) to 10 (worst possible pain) immediately after graft harvesting. Then, the donor site was temporarily covered with 1:200 000 epinephrine-soaked gauze.

Debridement of the recipient site was performed with or without 2% lidocaine injection. If any area of necrotic tissue required deeper debridement, lidocaine injection was used on the relevant area. However, in most cases, the wound beds were well prepared, requiring only simple cleansing or superficial curettage. The graft was then fixed to the wound with tapes, staples, sutures, fibrin glue, or negative pressure wound therapy (NPWT). The grafted area was then covered with an indirect wet dressing over petroleum gauze and a splint was used to immobilize the extremity. Pain in the recipient site during debridement and graft fixation was rated by patients as none, mild, moderate, or severe. Last, the donor site dressing was changed to Biatain® Ibu foam dressing (Coloplast, Humlebaek, Denmark) and the patient was returned to their ward. The STSG procedure performed under TA can be viewed in a video shown on https://youtu.be/KMuoZvEsTw8.

The surgical procedure was the same for the GA/SA group; however, these patients were kept in the postoperative recovery room (POR) after surgery for about 1 hour. Patients in whom prolonged extubation was anticipated and required were sent to the intensive care unit. In both groups, the recipient site wound dressing was changed on postoperative days 3, 6, 10, and 14, and the donor site dressing was removed on day 14.

2.3. Data and outcome analysis

Patient demographics and clinical characteristics, and wound etiology, location, and size were recorded. The wound etiology was categorized into infection, trauma and burn. If the patients had the wounds >1 month or underwent STSG in a separate hospitalization from previous debridement, the etiology would be

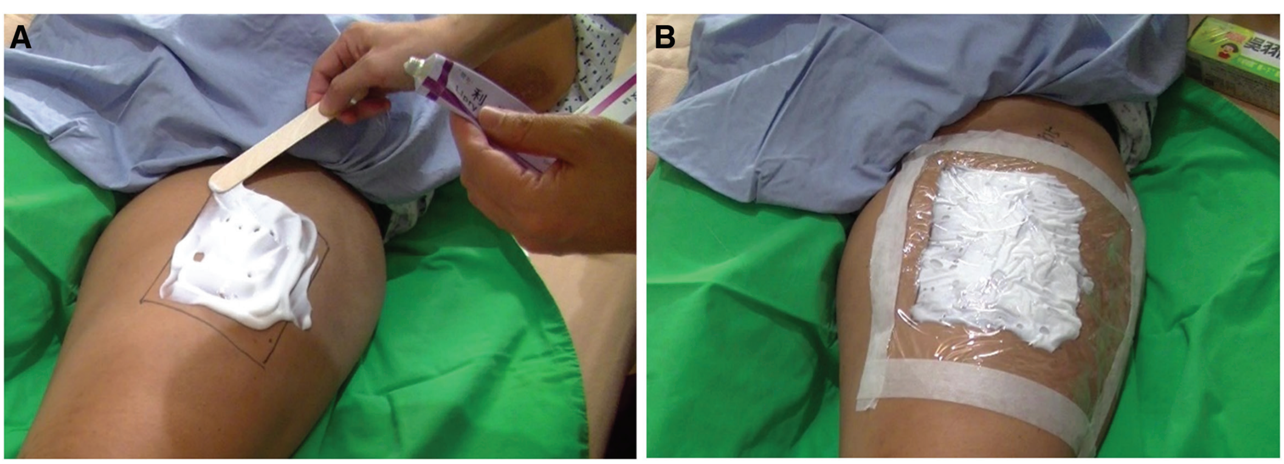

Fig. 1 Preoperative application of an EMLA to a skin graft donor site. A, The EMLA cream was applied evenly. B, Covered by a plastic dressing. EMLA = eutectic mixture of lidocaine and prilocaine.

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defined as chronic ulcer. The physical condition of each patient was evaluated using the Charlson comorbidity index (CCI) and American Society of Anesthesiology (ASA) Physical Status classification. Outcomes, including wound healing status, postoperative opioids use, length of hospital stay, and postoperative complications were also evaluated. Among the complications, wound infection was defined as erythematous swelling or pus presented at the recipient or donor sites with positive culture. The medical expenditure was calculated by New Taiwan Dollar (NTD) at the rate of 1 NTD: 0.035 US dollar.

To compare glucose control between the two groups, serum glucose levels were obtained on the day of surgery and 24 hours postoperatively. Glucose variability (GV) was defined as the standard deviation of glucose measurements within a certain period. Patients subject to a once-daily glucose check were excluded from GV calculation. Hypoglycemic events were defined as blood glucose <70 mg/dL and hyperglycemia as blood glucose >200 mg/dL.

For statistical analysis, Mann–Whitney U tests were used to compare continuous variables, and chi-square or Fisher exact tests were used for categorical variables. Analyses were performed using SPSS v. 24 software for Windows (SPSS, Inc., Chicago, IL, USA). In all cases, $p < 0.05$ was considered statistically significant.

3. RESULTS

Between January 2018 and December 2020, 74 diabetic patients (44 males, 30 females; mean age, 60.1 ± 12.2 years; range 36–91) undergoing lower limb STSG were included in this study. There were 28 patients under TA and 46 patients under GA or SA. Among the GA/SA group, most of these patients received GA, with only two patients receiving SA. Overall, the most common wound etiology was infection (73.0%), followed by trauma (12.2%) and chronic ulcer (12.2%). The demographic and clinical data were listed in Table 1, and there were no significant differences between the two groups in age, gender, body mass index, wound etiology, skin graft fixation methods, CCI, ASA class, HbA1c, or defect size; however, the TA group had undergone less debridement procedures (TA = 1.5 ± 1.3, GA/SA = 2.5 ± 1.6, p = 0.016). This may be due to the TA patients having relatively higher anesthesia risk (ASA III: 57.1%, IV:7.1%) and, therefore, undergoing more bedside debridement.

For the STSG surgery of patients under TA, the average anesthetic cream application time was 217.0 ± 87.1 minutes, and the average amount of cream applied was 16.0 ± 3.4 g/100 cm^2. All surgeries were successfully performed without the need for conversion to GA or SA. Pain during skin grafting was generally tolerable, with a mean VAS score of 0.98 ± 1.37. There was no pain at the recipient site in 67.9% of the patients and the other 32.1% only reported mild pain during the procedure. Postoperatively, fewer patients in TA group were given opioids (TA = 14.3%, GA/SA = 43.5%, p = 0.01), and the total dose of opioids within 3 days after conversion to the equianalgesic dose of intravenous morphine was also significantly less than the GA/SA group (TA =1.6 ± 4.6, GA/SA = 8.4 ± 19.3 mg, p = 0.01).[9]

At the 4-week follow-ups, the graft had completely taken and the wound had completely healed in the majority of the TA patients (82.1%). Only five patients under TA (17.9%) had partial graft losses. The wound healing rates were similar between groups at postoperative weeks 2 and 4. There was no significant difference in the overall or pregrafting hospital stay but most of the participants of the TA group were discharged earlier after skin grafting (postgrafting hospital stay: TA = 8.3 ± 6.2, GA/SA = 11.1 ± 7.2 days, p = 0.048). Two patients in the GA/SA group were transferred to the intensive care unit for prolonged postoperative respiratory recovery. Patients who underwent STSG under TA had lower surgical costs (21292 ± 13774 vs 39443 ± 16743 NTD, p < 0.001) (Table 2).

Table 1

Demographics and clinical characteristics of diabetic patients who underwent split-thickness skin graft surgery under topical anesthesia or general/spinal anesthesia

	TA (n = 28)	GA/SA (n = 46)	*p*
Age (y)	61.6 ± 13.8	59.2 ± 11.2	0.64
Gender			0.81
Male	16 (57.1%)	28 (60.9%)	
Female	12 (42.9%)	18 (39.1%)	
Smoking	6 (21.4%)	9 (19.6%)	0.85
Body mass index (kg/m^2)	27.4 ± 5.4	26.5 ± 5.3	0.53
Etiology of wound			0.89
Infection	19 (67.9%)	35 (76.1%)	
Trauma	4 (14.3%)	5 (10.9%)	
Burn	1 (3.6%)	1 (2.2%)	
Chronic ulcer	4 (14.3%)	5 (10.9%)	
Pregrafting debridement	1.5 ± 1.3	2.5 ± 1.6	0.016
Defect size (cm^2)	46.4 ± 36.9	47.3 ± 38.2	0.85
Graft fixation method			0.098
Staple/suture	11 (39.3%)	17 (37.0%)	
Sterile tape	9 (32.1%)	7 (15.2%)	
Fibrin sealant	1 (3.6%)	0	
NPWT	7 (25%)	22 (47.8%)	
HbA1c	9.1 ± 2.9	8.8 ± 2.8	0.64
CCI	4.6 ± 2.1	4.2 ± 2.0	0.4
ASA level			0.065
II	10 (35.7%)	26 (56.5%)	
III	16 (57.1%)	20 (43.5%)	
IV	2 (7.1%)	0	

ASA = American Society of Anesthesiology Physical Status classification; CCI = Charlson comorbidity index; GA = general anesthesia; NPWT= negative pressure wound therapy; SA= spinal anesthesia; TA = topical anesthesia.

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Table 2

The wound healing outcomes, length of hospital stay, and medical costs of diabetic patients who underwent split-thickness skin graft surgery under topical anesthesia or general/spinal anesthesia

	TA (n = 28)	GA/SA (n = 46)	*p*
Wound healing status			
Healing in 2 wks	22 (78.6%)	34 (73.9%)	0.65
Healing in 4 wks	23 (82.1%)	34 (73.9%)	0.41
Postoperative opioids[a]			
Number of patients used	4 (14.3%)	20 (43.5%)	0.01
Cumulative dose (mg)	1.6 ± 4.6	8.4 ± 19.3	0.01
Length of hospital stay			
Overall (d)	17.9 ± 13.5	23.5 ± 16.1	0.15
Pregrafting (d)	10.1 ± 12.9	14.6 ± 13.2	0.15
Postgrafting (d)	8.3 ± 6.2	11.1 ± 7.2	0.048
Cost			
Operation day (NTD)	21 292 ± 13 774	39 443 ± 16 743	<0.001
Total cost (NTD)	141 954 ± 125 151	212 056 ± 174 263	0.054

GA = general anesthesia; NTD = New Taiwan Dollar (1 NTD = 0.035 US dollar); SA = spinal anesthesia; STSG = split-thickness skin grafting; TA = topical anesthesia.

[a]Postoperative opioids were only analyzed within 3 days after STSG surgery. The cumulative dose of opioids is the sum of all forms of opioids drugs by the equianalgesic dose ratios conversion and presented as IV form morphine dose.[9]

Postoperative complications are shown in Fig. 2. Although there seemed to be a trend that TA group had less complication, the difference was not statistically significant (eg, wound infection rate: TA = 3.6%, GA/SA = 15.2%, $p = 0.25$). However, when considering the overall postoperative infections (including pneumonia and wound infection), the GA/SA group had significantly more infection complications (TA = 3.6%, GA/SA= 21.7%, $p = 0.044$). One patient in the GA/SA group, a 78-year-old woman, suffered both wound infection and a stroke postoperatively. On the 14th day after skin grafting, she had a cardiac arrest, thought to be acute myocardial infarction. This patient died after a failed attempt at resuscitation.

The GA/SA group had a similar incidence of hypoglycemia but more hyperglycemia events on the day of surgery and in the subsequent 24 hours. As can be seen in Fig. 3, the TA group had a lower mean glucose level and less GV on the day of surgery and in the subsequent 24 hours, indicating better blood glucose control.

3.1. Case One

A 63-year-old woman with a history of hypertension and poorly controlled diabetes presented with a necrotizing soft-tissue infection (NSTI) of the left foot and big toe (Fig. 4). An empirical antibiotic (ampicillin/sulbactam, 1500 mg Q6h) was given, and she was scheduled for debridement and big toe amputation. When the wound culture revealed the presence of methicillin-resistant *Staphylococcus aureus* and *Enterococcus*, vancomycin was added to her treatment.

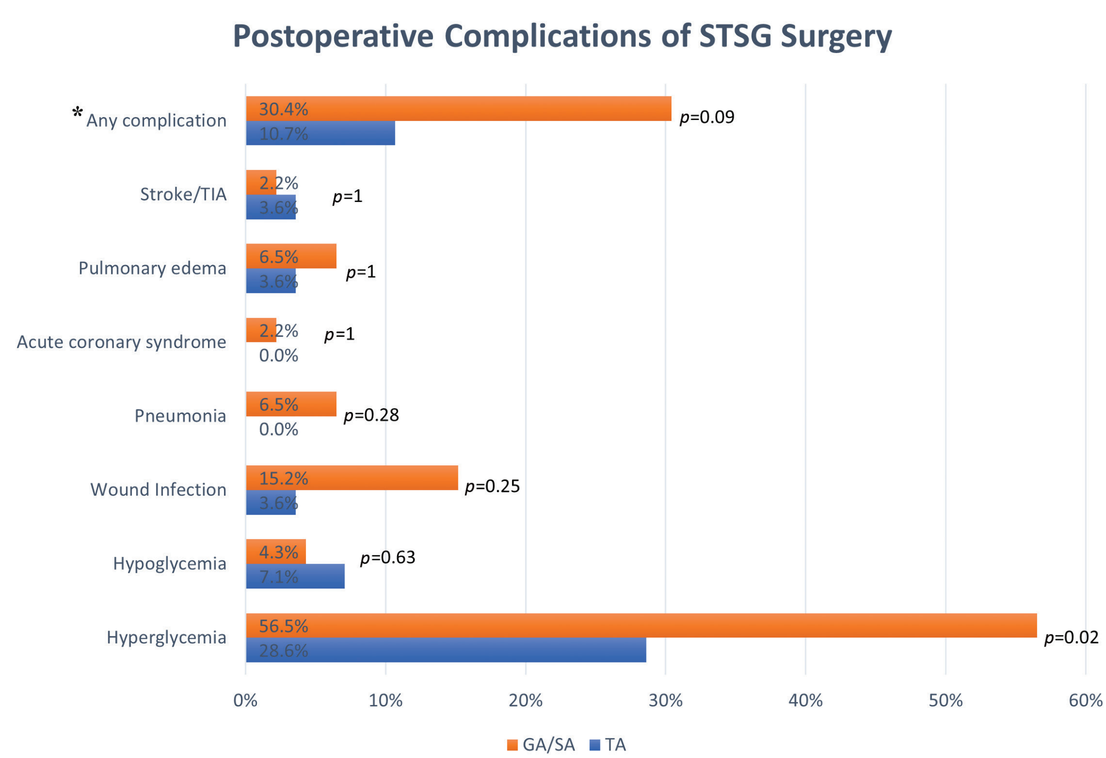

Fig. 2 Postoperative complications of split-thickness skin graft surgery. One patient in the GA/SA group had wound infection and stroke with subsequent cardiac arrest post-STSG surgery. *Hypoglycemia and hyperglycemia were not included in this category. GA = general anesthesia; SA = spinal anesthesia; STSG = split-thickness skin grafting; TA = topical anesthesia.

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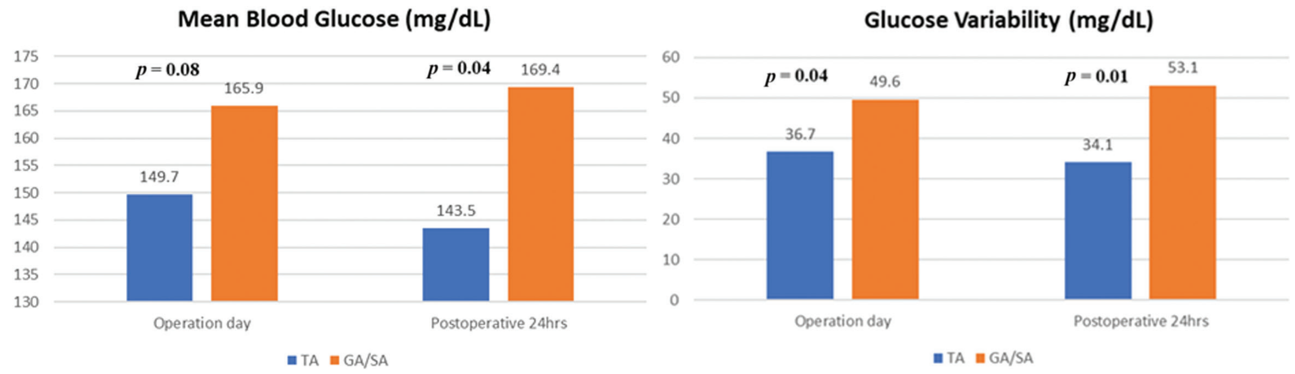

Fig. 3 Perioperative blood glucose parameters of patients who underwent split-thickness skin grafting (n = 67, 23 in TA group, 44 in GA/SA group). A, Mean blood glucose. B, Glucose variability. Patients subject to daily glucose checks were excluded. GA/SA = general anesthetic/spinal anesthetic; TA = topical anesthesia.

Fig. 4 A 63-year-old woman with left big toe and forefoot necrotizing soft-tissue infection. A, Initial presentation; (B) post big toe amputation and debridement; (C) 3 weeks postdebridement. D and E, STSG surgery under topical anesthesia fixed by negative pressure wound therapy; (F) One month post-STSG. STSG = split-thickness skin grafting.

The wound was cared for with a wet dressing, changed twice daily, and then NPWT was used 5 days later. After 2 weeks, the wound had improved, the infection had subsided, and the patient was ready for skin graft surgery. However, chest tightness and dyspnea developed, and the patient was diagnosed with non-ST segment elevation myocardial infarction. She underwent a percutaneous coronary angiography with stents. Considering the high anesthetic risk so soon after myocardial infarction, we performed STSG under TA. Postoperatively, the graft was fixed by NPWT, and the wound healed well with no further systemic complications. She was discharged nine days after STSG and the total length of hospital stay was less than one month.

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3.2. Case two

A 66-year-old male patient presented with left foot NSTI with plantar fascia involvement (Fig. 5). He was newly diagnosed with diabetes and his HbA1c was 12.2% on admission. He underwent debridement and antibiotic treatment (ampicillin/ sulbactam, 3000 mg Q6h). The wound culture revealed polymicrobial infection. This was gradually brought under control by the antibiotics, and he received two more sessions of debridement on days 4 and 11 (one under GA and one under local anesthetic). NPWT was used to accelerate granulation tissue growth. He underwent STSG with TA on day 25. The graft was fixed with tapes and limited sutures and took well postoperatively. The postoperative course was uneventful and he was discharged on day 36.

4. DISCUSSION

The use of STSG to treat large, deep, and complex foot or leg wounds in diabetic patients had been reported in many studies. Anderson et al. treated foot and leg ulcers in 107 diabetic patients with STSG, achieving a very high wound healing rate (>90%) and a low STSG-related complication rate (2.8%).[2] However, their patients were relatively healthy, with 60% having no comorbidities. Sanniec et al[10] have reported a graft failure rate of 37.2% with 43 surgical sites. Graft failure was found to be unrelated to high HbA1c.

A retrospective study by Ramanujam et al,[11] included 203 patients treated for foot wounds with STSG. They found that diabetes-associated comorbidities, such as peripheral vascular disease, nephropathy, and cardiovascular disease, conferred greater risks of graft failure than the diabetes itself.[11]

Previous studies of STSG for diabetic foot and leg wounds have addressed the success of the grafts or wound healing but have seldom discussed overall surgical or systemic complications or their relationship with methods of anesthesia. In our study, the wound healing rates were 82.1% in the TA group and 73.9% in the GA/SA group, which is compatible with previous reports. Nevertheless, most of our patients had multiple comorbidities and high CCI scores. It was for these reasons that TA was used to lower the risks of anesthesia and improve outcomes. Although wound healing was similar between groups, the TA group had fewer postoperative complications and could be discharged earlier, indicating better, faster postoperative recovery.

The relationship between perioperative glycemic control and postoperative complications has been well-studied. In diabetic patients, good preoperative glycemic control has been shown to reduce the length of hospital stay, the incidence of hypoglycemia, and the rate of mortality.[12,13] Elevated 24-hour postoperative glucose concentrations are positively correlated with postoperative infection rates in diabetic patients undergoing noncardiac surgery.[8]

We have demonstrated in this study that the use of TA in STSG surgery for diabetic patients can improve glucose levels on the day of surgery and the subsequent 24 hours. This may explain the lower incidence of infections in our TA group. The wound infection would not only prolong the hospital stay but also lead to skin graft failure. In our study, among the eight patients complicated with wound infection, six of them could not achieve wound healing at week 4. An advantage of STSG under TA is that, because no preoperative fasting is required, regular glucose control protocols are not interrupted, regardless of whether oral hypoglycemic agents or insulin are used. When

Fig. 5 A 66-year-old male patient presented with left plantar foot necrotizing soft-tissue infection. A, Initial presentation; (B) 10 days after debridement; (C) 25 days after debridement; (D) One week after split-thickness skin graft surgery was performed under topical anesthesia.

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GA is used for surgery, patients are also required to abstain from oral intake for 4–6 hours after the GA to avoid postoperative nausea and vomiting. This further interferes with glucose control in diabetic patients. In contrast, patients treated using TA can resume normal activity (from their bed) immediately after surgery, which is particularly advantageous when the surgery is short and simple, as is the case with STSG.

In our previous study, we demonstrated the effectiveness and efficiency of TA with EMLA during the skin harvesting process in STSG. TA was shown to be a good choice for patients with high anesthetic risks.[7] In the present study, we found that most diabetic patients with lower extremity wounds had multiple comorbidities and would benefit from STSG under TA. At our institution, STSG under TA is our first choice in treating diabetic leg and foot wounds if the patient agrees to this approach.

Based on a literature review and our experience, we have established that the application of at least 1.5 g/10 cm^2 EMLA 2–5 hours before surgery achieves good analgesic effects when skin graft harvesting.[5–7,14] However, patients can feel nervous or anxious during the procedure because they are fully awake. To alleviate this problem, we showed them an educational video demonstrating the procedure and provided assurance of the effectiveness of the procedure. Antianxiety drugs were also given before the patients were taken to the OR. These preoperative preparations increased the patients' acceptance of STSG under TA and helped with wider implementation of the procedure in clinical practice. Although most of the patients in this study had small to medium-sized wounds, the protocol and postoperative care of STSG under TA were similar for the larger wounds. However, we preferred to use fibrin glue for graft fixation in the large-sized wounds to achieve better healing and less pain.

There were some limitations to this study. The first of these was the relatively small sample size. This may have weakened the statistical power. The second was the lack of randomization due to the retrospective nature of the study. Although the two groups of patients had similar demographic and wound characteristics, a certain degree of selection bias would still exist because the methods of anesthesia were selected by the patients and surgeons. For example, the patients who had been selected to undergo TA might have better wound bed preparation and therefore yield lower wound infection results. Third, we did not have objective measurements of patients' peripheral neuropathy, for example, monofilament tests or neuroelectric studies. These data would have allowed us to predict patient pain tolerance and select the most suitable patients for STSG under TA. Last, TA only works in the area where the EMLA cream is applied. Thus, if a graft is not harvested successfully or is larger than expected, it would be troublesome to utilize a second donor site. To avoid this situation, applying the EMLA to a larger area, shifting to local anesthetic injection, or postponing surgery are possible alternatives.

In conclusion, conducting STSG under TA can effectively treat lower leg and foot wounds in diabetic patients. Compared with GA and SA, it can achieve better perioperative glucose control and lead to fewer postoperative infections. STSG under TA should be considered in patients with high anesthetic risk.

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