Trans tibial amputation with or without a tourniquet in patients with diabetic foot infection and peripheral vascular disease: Comparison of postoperative outcomes

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Abstract
Background: Transtibial amputation (TTA) due to complications of diabetic foot infection (DFI) or peripheral vascular disease (PVD) is a high-risk procedure in fragile patients. The risks of reoperation, blood loss requiring blood transfusion, and mortality are high. The use of a tourniquet in this procedure is controversial and scarcely reported. Objective: This study aimed to compare the outcomes of TTAs with or without a tourniquet in a single tertiary medical center. Methods: We retrospectively identified all patients who had undergone TTA in our institution (1/2019-1/2020) and included only those who underwent the procedure due to complications of DFI or PVD (n = 69). The retrieved data included demographics, comorbidities, ASA score, the use of a tourniquet, operation duration, pre- and postoperative hemoglobin levels, administration of blood transfusions, hospitalization length, surgical site infection and 60-days reoperation and mortality rates. Results: TTA with a tourniquet was superior to TTA without a tourniquet in reducing the average operation length by 11 min (p = 0.05), the median postoperative hospitalization by 6 days (p = 0.04), and the use of blood transfusions (odds ratio [OR] = 0.176, 95% confidence interval [CI]: 0.031–0.996). Conclusions: Our findings demonstrated advantages in operative time, hospitalization length, and blood transfusion requirement for TTA with a tourniquet compared to TTA without a tourniquet.

Keywords
Amputation, Tourniquet, Trans tibial, Below knee

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Introduction

Trans tibial amputation (TTA) in patients with diabetic foot infection (DFI) and peripheral vascular disease (PVD) is a major procedure that can result in massive blood loss and high mortality rates. DFI and PVD complications are responsible for the majority of lower extremity amputations. Eighty-two percent of all vascular-related lower extremity amputations in the USA are associated with diabetes mellitus (DM), and diabetic patients have 10-13 fold higher risk of undergoing lower limb amputation.

The patients undergoing TTA due to complications of DFI and PVD are often fragile and elderly, with high rates of...
comorbidities and are frequently in a state of septic shock at presentation. Among those comorbidities are ischemic heart disease (IHD), congestive heart failure (CHF), and chronic kidney disease (CKD). Therefore, any surgical intervention in this population, especially procedures associated with high blood loss, bears high risks of reoperation, blood loss requiring blood transfusion, and mortality.

Reduction of the blood loss can potentially increase the safety of the procedure. The use of a tourniquet in TTA in patients with PVD and DM is controversial, and evidence-based data on this controversy are limited. The theoretic risks of using a tourniquet in patients with atherosclerotic vessels are injury to the vessel and uncontrolled bleeding upon reperfusion. We are aware of only three studies that examined the use of a tourniquet in TTA in patients with DFI and PVD in the past two decades: they presented some benefits and no adverse outcomes.

The purpose of this retrospective analysis, therefore, is to compare the postoperative outcomes of TTA with and without a tourniquet in patients with DFI and PVD. We hypothesized that TTA with a tourniquet is superior in terms of blood loss and blood transfusion requirements, hospitalization time, and complications, and thereby improves the survivorship of these patients.

Materials and methods

Study design and data collection

This retrospective cohort study was conducted in a single tertiary medical center following approval of the institutional review board which waived informed consent. All of the patients who underwent TTA in our medical center between January 2019 and January 2020 were identified from the hospital database. Only patients who underwent TTA due to complications of DFI or PVD were included in the study. Data from the patients’ electronic records were collected, and they included baseline patient characteristics, such as age, sex, comorbidities (PVD, DM, IHD, CHF, CKD, end-stage renal disease [ESRD]), preoperative hemoglobin levels, ASA score, and whether the patient was in septic shock at presentation. Intraoperative data were retrieved from electronic operative reports, and they included operation duration, the use of blood transfusions, and the use of a tourniquet during the procedure. Postoperative data included hemoglobin levels, the use of blood transfusions, 60-days mortality, surgical site infection and the need for reoperation. The patients were followed throughout their hospitalization, inpatient rehabilitation, re-hospitalization within 60 days from the day of TTA, as well as their visits to the outpatient clinics 2 and 6 weeks following discharge.

Surgery

The patients underwent a standard TTA approximately 10 cm below the tibial tuberosity. In cases where a tourniquet was used, the tourniquet was inflated to 100 mmHg above the systolic blood pressure before making the incisions, and it was removed after completing the amputation and ligating of the vessels, before final hemostasis and closure of the stump. The decision to use a tourniquet was based upon the surgeon’s preference. The procedures were done by the same team of surgeons.

Statistical analysis

Continuous data are presented as mean ± standard deviations (SD) or median with interquartile ranges (IQRs), and categorical data are presented as percentage. Comparisons were made with the t-test or the Mann-Whitney U test for continuous variables, and the χ2 test or Fisher’s exact test was used for categorical variables. Comparisons of preoperative and postoperative hemoglobin levels and mean hemoglobin loss were performed with independent and paired samples t-tests. The associations between 60-days mortality, the use of blood transfusions, reoperations, the intraoperative use of a tourniquet, demographic characteristics, and comorbidities (age, sex, DM, ESRD, CKD, DM, IHD, CHF, septic shock, and ASA score) were analyzed by applying multivariate logistic regressions. The models used either 60-days mortality, the use of blood transfusions, or reoperations as the dependent variable, and all of the above-cited predictor variables along with tourniquet use as independent variables. A logistic regression model with tourniquet use as the dependent variable was performed to identify potential selection bias. A p-value of 0.05 or lower was considered statistically significant. Sample size analysis was performed by using winpepi v11.65, showing that in order to achieve statistical significance when comparing the average hemoglobin loss of the TTA with and without tourniquet groups, found in our study, a sample of 99 cases in each group was required. All analyses were performed by IBM SPSS v24.

Results

Between January 2019 and January 2020, 84 patients underwent TTA in our medical institution. After exclusion of TTA due to trauma or malignancy, our final cohort consisted of 69 patients (Figure 1). Twenty-nine patients were operated with the use a pneumatic tourniquet and 40 without a pneumatic tourniquet. There were no significant differences in demographic characteristics and comorbidities between the two groups (Table 1). The mean age of the patients was 67.7 (SD = 12.3) in the group operated with a tourniquet and 70.7 (SD = 11.9) in the group operated without a tourniquet (p = 0.32). Men were 86.2% and 77.5% of the group...
operated with tourniquet and the group operated without tourniquet respectively ($p = 0.36$). Diagnosis of DM was present in 79.3% of the patients operated with tourniquet and 90% of the patients operated without tourniquet ($p = 0.30$). PVD Diagnosis was present in 62.1% of the patients operated with tourniquet and 72.5% of the patients operated without tourniquet ($p = 0.36$). ESRD was present in 20% of the patients in both groups ($p = 0.94$). Septic shock during the operation occurred in 55.2% and 47.5% of the cases operated with or without tourniquet respectively ($p = 0.53$). IHD, CHF, mean ASA score and mean preoperative hemoglobin levels also did not differ between the groups and are presented in Table 1.

Table 1 displays the comparisons of operation and hospitalization lengths, 60-days mortality, surgical site infection and 60-days reoperation between the tourniquet and non-tourniquet groups. The mean operation length was 77.45 (SD = 19.23) minutes and 88.23 (SD = 26.17) minutes in groups of TTA with or without tourniquet respectively ($p = 0.05$). Median postoperative hospitalization time was 11 (9–15) days in the TTA with tourniquet group and 17 (11–26) days in the TTA without tourniquet group ($p = 0.04$). Sixty days mortality was 17.2% in the TTA with tourniquet group and 27.5% in the TTA without tourniquet group ($p = 0.32$). Reoperation within 60 days from the day of TTA was 20.7% in the TTA with tourniquet group and 30.0% in the TTA without tourniquet group ($p = 0.39$). Surgical site infection rate was 13.8% and 17.5% ($p = 0.68$) in the TTA with and without tourniquet groups respectively.

The preoperative and postoperative hemoglobin levels in g/dl, the mean perioperative hemoglobin reductions, the requirements of transfusion therapy and average number of transfusions used for the two groups are compared in Table 3. Hemoglobin loss was 0.24 g/dl in the TTA with tourniquet compared to 0.72 g/dl in the TTA without tourniquet group ($p = 0.29$). Transfusion therapy during the operation or the seven consecutive days was required in 27.6% of the cases in the TTA with tourniquet compared to 40.0% of the cases of TTA without tourniquet ($p = 0.29$). Average number of blood transfusions per case was 0.41 units in the TTA with tourniquet group compared to 0.70 units in the TTA without tourniquet group ($p = 0.25$) representing number needed to treat of 3.45 cases in order to spare one event of transfusion therapy.

Table 4 displays the results of multivariate logistic regressions comparing mortality and reoperations within 60 days and the use of blood transfusions between the patients who underwent TTA with and without a
tourniquet, accounting for the following covariates: DM, PVD, CKD, ESRD, CHF, IHD, ASA score, and septic shock. The patients who underwent TTA with a tourniquet had significantly reduced OR for the need to use blood transfusions: OR = 0.176 (p = 0.049, 95% CI: 0.031–0.996). The patients who underwent TTA with a tourniquet had a non-significant reduction in OR of mortality within 60 days from surgery and reoperation within 60 days from surgery when compared to TTA without a tourniquet (see Table 4). The multivariate logistic regression with tourniquet as the dependent variable and all other covariates as independent variables showed no significant ORs and therefore no potential selection bias.

**Discussion**

This retrospective study shows favorable postoperative results with the use of tourniquets in TTA compared to TTA without a tourniquet. The use of a tourniquet significantly reduced the average operation duration by 11 min (p = 0.05) and the median postoperative hospitalization by 6 days, i.e by more than one third (p = 0.04). The use of blood transfusions was also decreased in the TTA with a tourniquet group (OR = 0.176, 95% CI: 0.031–0.996). Moreover, there was a non-significant trend favoring the use of a tourniquet in the rates of mortality and reoperation within 60 days, which were lower by 10.3% (p = 0.32) and 9.3% (p = 0.39), respectively. Finally, the mean perioperative haemoglobin loss was lower by an average of 0.48 g/dl in the TTA in the tourniquet group, and there was a 13.4% reduction in the number of patients requiring blood transfusion therapy (p = 0.29). Neither of these results reached statistical significance. In addition, the average number of blood transfusions per patient was reduced by 0.29, however once again this was not statistically significant (p = 0.25). The number needed to treat to avoid the use of one blood transfusion was 3.45. All of these results showed a superiority of the postoperative outcomes of TTA with a tourniquet compared to TTA without a tourniquet.

We found three published studies which investigated this topic. Weid et al. conducted a retrospective cohort study on 74 patients who underwent TTA with or without the use of a tourniquet and found no difference in total

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**Table 2.** Comparison of operation and hospitalization lengths, 60 days mortality and 60 days reoperation.

|                        | TTA with tourniquet (n = 29) | TTA without tourniquet (n = 40) | p-value |
|------------------------|-----------------------------|---------------------------------|---------|
| Operation length (minutes) | Mean (SD) 77.45 (19.23) | 88.23 (26.17) | 0.05 |
| Postoperative hospitalization length (days) | Median (IQR) 11 (9–15) | 17 (11–26) | 0.04 |
| 60-days mortality (%) | 17.2% | 27.5% | 0.32 |
| Reoperation within 60 days (%) | 20.7% | 30.0% | 0.39 |
| Surgical site infection (%) | 13.8% | 17.5% | 0.68 |

**Table 3.** Comparison of hemoglobin levels, hemoglobin loss and transfusion therapy.

|                        | BKA with tourniquet (n = 29) | BKA without tourniquet (n = 40) | p-value |
|------------------------|-----------------------------|---------------------------------|---------|
| Preoperative hemoglobin (g/dl) | Mean (SD) 9.66 (1.18) | 9.76 (1.38) | 0.76 |
| Postoperative hemoglobin (g/dl) | Mean (SD) 9.42 | 9.04 | 0.27 |
| Mean perioperative hemoglobin reduction (g/dl) | Mean (SD) 0.24 | 0.72 | 0.13 |
| Transfusion therapy (%) | 27.6% | 40.0% | 0.29 |
| Average number of transfusions | Mean (SD) 0.41 (0.7) | 0.70 (1.14) | 0.25 |

**Table 4.** Odds ratio of postoperative outcomes of BKA with tourniquet compared to without tourniquet (reference group).

|                        | Odds ratio (OR) | CI | p-value |
|------------------------|-----------------|----|---------|
| Mortality within 60 days | 0.33 | 0.001–1.112 | 0.057 |
| Use of blood transfusion | 0.176 | 0.031–0.996 | 0.049 |
| Reoperation within 60 days | 0.212 | 0.025–1.79 | 0.154 |
blood loss ($p = 0.754$) or in re-amputation rate ($p = 0.78$). Wolthuis et al.’s prospective non-randomized study of 89 cases demonstrated significant reduction in blood loss, blood transfusion rates, and re-operation rates. The results of a prospective randomized blinded controlled trial of 64 cases by Choksy et al. showed a significant reduction in blood loss and in the use of blood transfusions in TTAs with a tourniquet, with no difference in wound healing, breakdown, or revision rates between the tourniquet and non-tourniquet groups. Mohd et al. compared the outcomes of transfemoral amputation with and without a tourniquet in a randomized controlled study of 40 cases and reported a significant reduction in blood loss and in the use of blood transfusions, with no significant difference in wound breakdown or reoperation rates between the tourniquet and non-tourniquet groups. Bruce et al. studied published outcomes of total knee arthroplasties with a tourniquet in patients with impalpable foot pulses or with claudication, and concluded that it is safe to operate on this group of patients with a tourniquet.

We attribute the decreased operative time, which we found when tourniquet was used, to the easier bleeding control and the increased efficiency of the hemostasis when a tourniquet is used.

This study has some limitations that bare mention. One is the size of the groups, which precluded the establishment of statistical significance in several outcome parameters. However, our study did not differ much in size from other publications of this topic. Additionally, it is retrospective, non randomized nor controlled and the use of tourniquet was decided according to surgeon’s preference.

In conclusion, TTA associated with PVD and DM is a highly morbid procedure on extremely fragile patients. It has high rates of blood loss, need for blood transfusions, reoperation, and mortality. The findings of the current report indicate that TTA is safer with the use of a tourniquet. We believe that this benefit originates in reduction of blood loss and easier maintenance of adequate blood pressures during the operation, which in this fragile patient population has a substantial effect on increasing the procedure’s safety. Further studies are indicated in order to achieve higher statistical power and better understanding of the influence of a tourniquet in these operations.

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