A Comparative Study between Surgical Techniques by Local Excisional Debridement with a Xylocaine Block and Excisional Debridement under General Anesthesia, in Necrotizing Fasciitis

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Abstract:

Objective: This study aimed to compare the clinical and economic outcomes between excisional debridement with a local xylocaine block (LAD) and excisional debridement under general anesthesia (GAD).

Material and Methods: This retrospective medical record review was designed to review records of excisional debridement in necrotizing fasciitis (NF) at Sisaket Hospital from January 1, 2017, to December 31, 2019. Outcome measures were clinical outcomes at the preoperative time (baseline data, door-to-operating room), peri-operative time (operating time, blood loss, number of reoperations), postoperative time (mortality rate, length of stay, pain score, opioid drug use), types of NF, and direct costs of treatment by the provider's perspective. Descriptive statistics, chi-square and Mann-Whitney U test were used.

Results: The results of 245 patients showed that LAD was superior to GAD in terms of door-to-operating room time, lower operating time and blood loss, shorter length of hospital stay and lower cost of treatment. Moreover, the LAD showed a lower postoperative pain score, and less opioid drug use when compared to GAD. There were no significant differences in mortality rate, sites of infection and types of NF.

Conclusion: LAD showed better clinical outcomes and lower cost of treatment when compared to GAD in the treatment of NF. Nevertheless, excisional debridement under a LAD could be a choice for small wounds at the lower extremities in hospitals with limited resources, and insufficient numbers of anesthesiologists.

Keywords: excisional debridement, general anesthesia, local anesthesia, necrotizing fasciitis, outcome, xylocaine block

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Introduction

Necrotizing fasciitis (NF) is a rapidly progressing disease with a high mortality rate. The first description of the "modern" NF was reported by Joseph Jones in 1871. He found 2,642 patients with it, in a hospital during the American Civil War, and it had a mortality rate of 46 percent¹. On the other hand, the disease would progress slowly for several weeks which is unpredictable and could not be explained². The global incidence of NF is 0.4 per 100,000 population in males³. The mortality rate is as high at 16–30% which varies from area to area and depends on risk factors^{4,5}. In Thailand, the incidence of NF is 31.1 per 100,000 population. The incidence in males is 1.5 to 1 per 100,000 population. The commonly infected areas (over 80% of NF patients) are at the lower extremities with a mortality rate of 6.3%⁶.

At Sisaket Hospital, the incidence of NF in 2010 was 10.2 per 100,000 population. The death rate was 13.4%⁷. The mortality-related factors were chronic renal failure, age over 70 years, and sepsis⁷. Currently, there are four types of NF classified by the causative pathogens of infection. Type I is caused by anaerobes. Type II is caused by Streptococcus spp. Type III is caused by *Clostridium species*, gramnegative bacteria, *Vibrios spp., Aeromonas hydrophila.* And Type IV is caused by *Candida spp., Zygomycetes spp*⁸. The number of pathogens may vary from area to area. Thus, the diagnosis must be confirmed by culture. The treatment must be surgical excision, good postoperative care, and adequate nutrition⁹. The amount of tissue that needs to be excised, however, is a controversial issue because the skin in the extremities usually appears normal¹⁰.

A review showed that surgery time, that is less than 12 hours, reduced the mortality rate by 7.5 times¹¹. Surgery performed over 24 hours showed a 9–fold increase in mortality rates¹². The traditional research focused on aggressive surgical debridement to remove as much of the necrotic tissue as possible in one operation¹³. A research study showed that excessive surgery increased amputation and mortality rates¹⁴. Thus, patients with infection in the extremities should have surgery in order to remove the necrosis only in the infected area¹⁵⁻¹⁷. This was also confirmed by the general consensus that careful trimming of necrosis on the soft tissue is required¹⁴. In Europe and America, the NF was found mainly at the abdominal wall, genitalia, sacrum, buttock and perineum¹⁸. Fournier's gangrene was a predominant type of NF^{19,20}. Some patients who reserve intensive care units and pulmonary function should consider surgical management under general anesthesia (GAD), which is a good choice²¹.

There are different surgeries performed on NF patients, including by local excisional debridement with a xylocaine block, spinal block, or GAD. The choice of appropriate lidocaine anesthetic technique is dependent on patient status, duration of operation, skill of the operator, degree of sepsis, wound size, the site of infection, and the stage of coagulopathy. In regards to patients with a history of lidocaine allergy, the regional and local anesthesia should be avoided. In some situations, patients have to be moved to more than one position; including the prone, lateral and lithotomy positions, making anything other than GAD more of an anesthetic challenge²².

Based on the literature review, local anesthesia in widespread surgery can block nerve endings and axons. In regards to a peripheral nerve block, surgical anesthesia can be injected from the skin layer, deep into the fascia and muscles^{14,23}. The maximum dose of xylocaine could be up to 300 mg, provided that there is no patient allergy history¹⁹⁻²¹. Epinephrine 1 in 200,000 has also been used to help stop bleeding. Furthermore, the concentration can be diluted to 1% or 0.5% in respect of lidocaine, for local anesthesia²⁴. In addition, a consecutive series of NF reported that bedside biopsy under local anesthesia with

an immediate frozen section evaluation of the inflammatory process and debridement improved survival rate²⁵. The use of local anesthesia for removing a necrotic tissue is commonly used in patients who have small wounds. The lesion at lower extremity and foot has an estimated mean size of infection of 9.7 cm² (in a pilot study, the lesions were 10.8 cm² in local xylocaine block (LAD) and 8.6 cm² in GAD, respectively), considering small size, thus, local anesthesia can be performed. The best surgery is that the patient needs quick access to the surgery, adequate surgical debridement, less time operation, safe surgery, lowest pain score after an operation, and low cost. From the aforementioned literature review, there were no studies comparing clinical outcomes between excisional debridement surgery using local anesthesia and GAD in NF. Therefore, this study was aimed to compare clinical outcomes between the excisional debridement with a LAD and excisional debridement under GAD at the preoperative, peri-operative, and postoperative times as well as in regards to types of NF, and the total direct costs of treatment.

Material and Methods

This study was approved by the Research Ethics Committee of The Sisaket Hospital under SSKH REC No. 052/65 E. This retrospective clinical record review was undertaken at Sisaket Hospital.

Inclusion and Exclusion Criteria

The inclusion criteria were patients who received excisional debridement under LAD and under GAD for NF as listed in the Sisaket Hospital database from January 1, 2017, to December 31, 2019. Medical records of NF with excisional debridement were identified as per ICD10 of M726, and ICD9 of CM 86.22. Patients with excisional debridement under spinal block or other procedures and patients who died before an operation were excluded.

Definition: NF diagnostics in ICD10 (code: M726)

1. It must be described as swelling, redness and hemorrhagic bleb with infected deep to fascia combined with pain.

2. A high-solution ultrasound may be performed to detect fluid in the fascia layer.

 An excisional debridement must be performed or the operative note must describe gangrene or necrosis fascia.

When operated by non-excisional debridement, the diagnosis was cellulitis. Therefore, in this research, patients diagnosed with NF according to the principles of ICD will be used, who also had excisional debridement (ICD9-CM 86.22).

Sample size

A pilot study was conducted using a sample of 10 participants in each group, both GAD and LAD groups, to calculate the sample size the n4Studies application was used.

The sample size for the two independent groups was estimated based on two independent means of equal samples. The length of hospital stay in GAD was 9.60 ± 10.67 (23), in LAD it was 2.90 ± 2.92 . The minimum sample size was 22 people per group (with α =0.05, two-tailed) with 80% power to reject the null hypothesis in regards to the length of hospital stay.

Procedures

All medical records of excisional debridement under a LAD and under GAD as a treatment for NF were retrieved. Data extraction was designed using a google sheet to collect data at the preoperative, peri-operative, and postoperative times. The total direct cost of treatment was analyzed using only the provider's perspective. It included medications, surgical procedures, labs, and other costs on each admission. 1. At the preoperative time, the data included age, gender, underlying disease, sites of infection, history of trauma, vital signs on admission day (body temperature, pulse, systolic pressure), the onset of disease, door-to-operating room time, preoperative laboratory test (HCT, CBC, platelet, BUN, creatinine, HCO₃, blood sugar). The sites of infection were divided into 4 groups: upper extremities, lower extremities, buttock, and others including genitalia, back, frank and the abdominal wall.

2. In regards to the peri-operative time, the data included the surgical technique, and types of anesthesia operating times, number of reoperations, and blood loss.

3. In regards to the postoperative time, the data included mortality rate, the length of hospital stay, pain score at day1 day2 day3, opioid drug use (postoperative mg of morphine used on Day1, Day2, Day3), and the total direct costs of treatment. The pain score used a rating scale of 0 to 10. Zero was no pain and 10 was the worst pain that the patient had ever felt, as reported by patients.

4. Types of NF

Steps of local excisional debridement with a LAD:

1. Evaluate patients with no history of allergic reactions to anesthetics; assess wound size and where the appropriate amount of xylocaine can be applied.

2. Use 0.5-1% xylocaine with Epinephrine 1 in 200,000(1mg/kg BW). An anesthetic is injected around the wound above demarcation at approximately 1 cm and field block to the site of the infection deep in the fascia.

3. Test the action of xylocaine. After that, an incision is made 1 cm above the demarcation area and Metzenbaum scissors are used to remove the necrotic tissue up to the muscle beneath the necrotic fascia.

4. Stop the bleeding point. Clean the wound and close it.

5. Assess the wound daily.

Statistical analysis

All data were compared between the LAD and GAD groups. Descriptive statistics were used. Categorical variables were compared using the chi-squared test, and continuous data were compared using the independent t-test for normally distributed data as well as the Mann-Whitney U test for data with non-normal distribution. STATA Program version 13 was used to analyze statistics.

Results

There were 245 patients who received the excisional debridement in NF and were included in this study. Sixty-five patients (26.4%) received excisional debridement under local LAD and 180 patients (73.5%) received excisional debridement under GAD.

The comparisons at the preoperative time between LAD and GAD

Comparing preoperative data between the LAD and GAD groups, There were statistically significant differences between groups in having diabetes, the history of trauma, and door-to-operating room time (p-value<0.05) as shown in Table 1.

The comparisons at the peri-operative time between LAD and GAD

When comparing the peri-operative data, LAD had a shorter operating time than GAD (p-value<0.05) and LAD had less blood loss than GAD (p-value<0.05) as shown in Table 2. The number of patients who received reoperations for the 2nd, 3rd, and 4th in the LAD group was less than in the GAD group.

The comparisons at the postoperative time between LAD and GAD

When comparing the postoperative outcomes, the mortality rate of LAD and GAD were 3.08% and 2.22%,

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| Variable | LAD n=65 | GAD n=180 | n-valuo |
|---|--------------|--------------|----------|
| Variable | LAD II=00 | GAD II=180 | p-value |
| Gender n (%): Male | 46 (70.77%) | 119 (66.11%) | 0.492 |
| Age (years) (mean±S.D.) | 56.49±18.86 | 56.11±11.25 | 0.940 |
| Sites of infection | | | 0.484 |
| Lower | 56 (86.15%) | 157 (87.22%) | |
| Upper | 9 (13.85%) | 18 (10.00%) | |
| Buttock | 0 (0.00%) | 1 (0.56%) | |
| Other | 0 (0.00%) | 4 (2.22%) | |
| Diabetes mellitus n (%) | 14 (21.54%) | 66 (36.67%) | 0.026* |
| Chronic renal failure n (%) | 13 (20.00%) | 54 (30.00%) | 0.121 |
| Liver disease n (%) | 2 (3.08%) | 17 (9.44%) | 0.100 |
| History of trauma n (%) | 49 (75.38%) | 90 (50.00%) | 0.000* |
| HCT (%) (mean±S.D.) | 32.43±6.22 | 30.61±6.67 | 0.062 |
| HCO, (mEq⁄l) (mean±S.D.) | 23.11±3.40 | 22.30±4.63 | 0.097 |
| Onset of disease(day) (mean±S.D.) | 6.31±8.68 | 5.60±5.64 | 0.081 |
| (median, IQR) | 4 (2, 7) | 5 (3, 7) | |
| Door-to-operating room time (hr.) (mean±S.D.) | 5.37±4.50 | 8.48±4.39 | <0.0001* |
| (median, IQR) | 5 (1, 8) | 8 (5.5, 11) | |
| BT (°C) (mean±S.D.) | 37.52±1.04 | 37.45±0.95 | 0.694 |
| Pulse (bpm)(mean±S.D.) | 96.93±87.56 | 91.20±14.37 | 0.018 |
| S systolic blood pressure (mmHg) (mean±S.D.) | 122.89±18.80 | 123.37±51.69 | 0.191 |
| Blood Sugar (mmol⁄l) (mean±S.D.) | 131.23±66.91 | 155.72±8.17 | 0.158 |

Table 1 Comparing preoperative data between LAD and GAD groups

*Mann-Whitney U test, IQR=interquartile range

"Other (site of infection): Genitalia=1 case, back=1 case, frank and abdominal wall=1 case.

HCT=Hematocrit, HCO₃=serum bicarbonate, BT=body temperature, BP sys=systolic blood pressure, LAD=local xylocaine block, GAD=general anesthesia, mmHg=millimeter of mercury, mmol/I=millimoles per liter

Table 2 Comparing peri-operative outcomes between the LAD and GAD groups

| Variable | LAD n=63 | GAD n=180 | p-value |
|-----------------------------------|-------------|-------------|----------|
| Operating time (Min.) (mean±S.D.) | 15.85±6.82 | 26.40±12.53 | <0.0001* |
| Blood loss (cc) (mean±S.D.) | 15.31±8.14 | 49.55±63.58 | <0.0001* |
| (Median, IQR) | 10 (10, 20) | 20 (20, 50) | |
| Number of reoperations (times) | | | |
| Second operation | 2 (3.17%) | 32 (17.77%) | |
| Third operation | 1 (1.58%) | 8 (4.44%) | |
| Fourth operation | 0 (0.00%) | 2 (1.11%) | |

*Mann-Whitney U test

IQR=interquartile range, LAD=local xylocaine block, GAD=general anesthesia

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respectively. LAD showed statistically significant differences in the shorter length of stay (p-value<0.05), lower postoperative pain score on Day 1, Day2, Day3 (p-value<0.05), less opioid drug use (p-value<0.05) and lower total direct costs of treatment than GAD (p-value<0.05) as shown in Table 3.

The comparisons of the types of NF between LAD and GAD

From the classification of NF according to the pathogens, there were no statistically significant differences as shown in Table 4.

Discussion

The treatment of NF by surgery showed that patients in the LAD group had a lower door-to-operating room time than GAD group. The comparison of perioperative outcomes between the LAD and GAD groups revealed that not only operating time and blood loss were significantly greater than in the GAD group, but also the number of reoperations was much higher in the GAD group. This implies that the severity of the NF between each group may be different, GAD may be more severe than LAD due to the number of GAD with diabetes mellitus having more than LAD, which may impact the choice of anesthesia.

In regard to the peri-operation time, LAD had better surgical outcomes vs. GAD, as well as shorter time operation, lower blood loss, and lower number of reoperations. In regards to the postoperation time, the LAD group had a shorter length of stay, lower pain scores, less opioid drug use and lower total direct costs of treatment.

A report revealed that LAD could slow the progression of NF for several weeks². An explanation is that LAD is more likely to be caused by trauma, and the number of patients with diabetes mellitus is statistically lower in Table 1. However, an adequate surgical excisional debridement should be a procedure that is simple, and easy to perform in every hospital, enhancing the quality of life of patients, with low pain and is highly cost-effective. Excisional debridement under GAD in Europe and America was used to treat Fournier's gangrene predominated in the abdomen, sacrum, genitalia and perineum¹⁶. This study might have a benefit of local anesthesia over GAD in regards to patients with small lesions on their extremities or patients who need serial debridement.

The number of reoperations in the LAD group was fewer than in the GAD group, however, there was no statistically significant difference. Most patients in Sisaket, Thailand experienced foot infections. A pilot study showed that the sizes of the wounds were 10.8, 8.6 cm² in LAD, and GAD, respectively. The average wound had a size of 9.7 square centimeters, which was not too large. However, the medical records in this study did not provide information about the size of the wounds, which was a limitation of this study. The choice of appropriate anesthetic technique is depending on the infected site, size of the infected wounds, patients' status, duration of the operation, and skill of operators.

In rural areas, there is still a shortage of anesthesiologists. In this situation, surgeons will have worried about using early LAD with excisional debridement. Furthermore, a report showed that the early bedside local anesthesia with biopsy and frozen section evaluation and treatment of an inflammatory process and immediate surgical debridement improved survival in NF patients²⁵. This study showed the benefits of LAD over GAD in terms of door-to-operating room time, lower operating time and blood loss, shorter length of hospital stay and cost-effectiveness. The limitation of using the LAD method is that it should not be used in patients with large wounds, a site of infection other than extremities, that is hemodynamically unstable, who have a rapid progression of infection and who have a history of allergic reactions to anesthetics.

| Variable | LAD n=63 | GAD n=180 | p-value |
|--|-----------------------|-------------------------|---------|
| Mortality | 2 | 4 | 0.702 |
| (Mortality rate) | (3.08%) | (2.22%) | |
| Length of stay(days) (mean±S.D.) | 3.37±2.88 | 7.76±11.55 | 0.0004* |
| (Median, IQR) | 2 (1, 4) | 3 (2, 7) | |
| Total direct costs of treatment (Baht) (mean±S.D.) | 10,521.40±3,954.78 | 26,072.71±25,105.30 | 0.0001* |
| (Median, IQR) | 9,881 (8,910, 13,000) | 15,348 (11,756, 29,319) | |
| Pain score day1 (mean±S.D.) | 3.56±0.73 | 4.25±0.95 | 0.0001* |
| (Median, IQR) | 3 (3, 4) | 5 (4, 5) | |
| Painscore day2 | 2.93±0.49 | 3.68±0.93 | 0.0001* |
| (mean±S.D.) | | | |
| (Median, IQR) | 3 (3, 3) | 4 (3, 4) | |
| Pain score day3 (mean±S.D.) | 2.68±0.47 | 3.20±0.85 | 0.0014 |
| (Median, IQR) | 3 (2, 3) | 3 (3, 4) | |
| Opioid drug use on Day1(mg) (mean±S.D.) | 1.15±1.96 | 4.79±2.78 | 0.0001 |
| (Median, IQR) | 0 (0, 3) | 4 (3, 6) | |
| Opioid drug use on Day2(mg (mean±S.D.)) | 0.00 ± 0.00 | 4.46±3.17 | 0.0001 |
| (Median, IQR) | 0 (0, 0) | 4 (3, 8) | |
| Opioid drug use on Day3(mg) (mean±S.D.) | 0.00 ± 0.00 | 2.90±2.55 | 0.0022 |
| (Median, IQR) | 0 (0, 0) | 3 (0, 4) | |

Table 3 Comparing postoperative outcomes between the LAD and GAD groups

*Mann-Whitney U test

Pain score: assessment using 0 to 10 numeric rating scale.

Opioid drug use(post-operative mg of morphine/day in day1, day2, day3).

IQR=interquartile range, LAD=local xylocaine block, GAD=general anesthesia

Table 4 Comparing the types of necrotizing fasciitis (NF) between LAD and GAD

| Type NF n (%) | LAD | GAD | p-value |
|---------------------------------------|-------------|-------------|---------|
| Type I: anaerobe | 21 (50.00%) | 78 (58.65%) | 0.271 |
| Type II: streptococcus+staphylococcus | 14 (33.33%) | 30 (22.56%) | |
| Type III: gram-, gram+ | 7 (16.67%) | 19 (14.29%) | |
| Type IV: fungus | 0 (0.00%) | 6 (4.51%) | |

*Mann-Whitney U test

LAD=local xylocaine block, GAD=general anesthesia

Conclusion

LAD is a practical procedure in the management of NF that showed better clinical outcomes and lower costs of treatment vs. GAD. However, the decision to use LAD should be based on wound size, progression of the disease, the sites of infection, and the skill of surgeon.

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Conflict of interest

None.

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