

Original Research Article

Pulsatile lavage for wound debridement in compound fractures of leg: a randomized control trial

Shafeed T. P.*, Bijopaul

Department of Orthopedics, Kerala Medical College, Palakkad, Kerala, India

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*Correspondence:

Dr. Shafeed T. P.,

E-mail: shafeedmarakar@gmail.com

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ABSTRACT

Background: Management of compound fractures is a real challenge to the orthopaedic surgeon. Thorough wound irrigation and debridement is necessary to get a good outcome. Power-pulsed lavage (PPL) is a method of wound irrigation that has been popularised as an adjuvant in wound debridement.

Methods: 39 patients of 28 to 40 years with Gustilo Anderson Type II and Type III fractures were divided in to two groups randomly and given pulsatile lavage or continuous flow lavage. Both the groups were followed up from January 2014 to January 2016, microbiology of the swab collected, pre and post lavage, and various other factors influencing the outcome were studied.

Results: Most of the successful outcome was in the age group of 25-29 years (46.7%) and in the male gender 66.7%. The success outcome rate was 73.3% in those with Type II Gustilo Anderson fracture compared to Type III (26.7%). All persons with successful outcome had Tscherne grade II fracture. Also a clean or clean contaminated wound (CDC classification) had more chance for successful outcome (86.7%) than contaminated or dirty wounds.

Conclusions: Heavy growth in pre-lavage blood agar culture was the single most important factor that determines the persistence of infection in compound fracture of both bones of leg. Type of lavage did not affect the union of fracture because presence of radiological signs of union was comparable in pulsatile group (66.7%) and continuous flow group (61.9%).

Keywords: Pulsatile lavage, Compound fracture, Heavy growth, Gustilo Anderson, Successful outcome

INTRODUCTION

Compound fractures remain one of the true orthopaedic emergencies. Bacterial contamination is present in as many as 70% of open fractures.¹ It is well recognized that the most critical element in the treatment of an open fracture is adequate wound debridement. Debridement of wounds was first described in the 18th century by Desault, and has since evolved to include a wide range of techniques, chief among them being thorough irrigation.² Wound irrigation is typically combined with debridement in order to remove infected and necrotic tissues and debris from the wound surface

and is generally considered to be standard surgical practice. Modern principles for the treatment of open fractures start from thorough wound debridement before stabilisation of the bone and management of the soft tissues. Wound debridement and irrigation is thought to be the mainstay in reducing the incidence of infection. New systems for debridement are currently being investigated, and an ideal method has yet to be determined.³ Pulsatile irrigation systems have been popularized as an adjuvant in wound debridement. Power-pulsed lavage (PPL) is a method of wound irrigation that uses an electrically powered pump system to deliver a high volume of an irrigation solution

under pressure. The pressure produced and volume delivered by a PPL system is generally considered greater than that produced with other standard methods of wound lavage. Normal saline should be used and although many antiseptics and antibiotics have been employed, no consensus has been reached as to the ideal additive. Despite the advocates of high-pressure methods highlighting the improved ability of such techniques, the results are inconclusive and these irrigation systems are not without complications. Although studies on animals and humans have focused on the wound irrigation, little is known of the factors which influence irrigation.

This study evaluates the evidence, particularly with regard to the mode of delivery of irrigation fluid i.e. pulsatile flow versus continuous flow method and factors affecting the outcome of lavage. A randomized control study was conducted on 39 persons with compound fractures of both bones leg. The effectiveness of lavage was evaluated by the absence of bacterial growth in culture from the wound taken prior to and after the lavage. The healing was also measured in terms of bone union (assessed radiologically) and by clinical examination. The factors affecting the outcome of lavage were also studied. This study can be considered as an earnest effort towards understanding the effectiveness of lavage particularly pulsatile lavage in wound debridement.

METHODS

Persons with in the age group of 25 to 40 years, presenting to the emergency room of the department of orthopaedics, sustaining open tibia fracture, with Type II and Type III compound fractures of tibia (Gustilo and Anderson) were included in the study.

Patient enrolment

The study population was divided by the block randomization. Each block of 4, comprises equal number of patients receiving either pulsatile irrigation or continuous irrigation. The study included total of 39 persons who received the continuous flow lavage or pulsatile lavage were studied from January 2014 to January 2016. They were divided into block of 4 persons, each comprising of equal number of patients who received either of one method. 18 persons received lavage by pulsatile method while 21 by the continuous flow method.

Exclusion criteria

Those who had Type I or Type III C (with associated vascular injury) and those patients who had severe other non-orthopaedic injury.

The persons in the study were divided into two groups according to whether they were given the continuous flow method or pulsatile lavage.

The procedure was done in emergency operation theatre under anaesthesia. After taking a swab specimen for culture and sensitivity, debridement was done. This was followed by lavage by selected method and surgical procedure. Another swab for culture and sensitivity was taken immediately after the lavage. For both the groups the wounds were flushed with 6 L of sterile normal saline for type II and 9 L for type III fractures. No additives like antibiotics were used. For continuous flow method pour bottle gravity assisted flow was employed. Pulsatile irrigation method was employed using a commercially available Mektronic pulsatile lavage system at 50 pounds per square inch (psi) of with continuous suction. The pre and post lavage swab for culture were taken from the deepest exposed surface of the wound and sent for microbiological assessment. Specimens procured for microbiological assessments were sent in standard transport tubes and carried out in the clinical laboratory of department of microbiology. Every specimen underwent microbiological assessments that included Gram stain analysis, bacterial culture and sensitivity analysis with blood agar, McConkey agar and salt agar. Gram stain indicated whether a gram positive or gram negative organism and culture indicated the type of organism.

The results of blood agar culture were analysed as no/scanty growth, moderate growth, heavy growth as given in Table1.

Table 1: Criteria of outcome.

Outcome	Culture growth
No growth	No growth in blood agar plate
Scanty Growth	Growth only at the site of inoculum in the blood agar plate
Moderate growth	Growth extending up to 2/3rd radius of the blood agar plate from the inoculums
Heavy growth	Growth extending from inoculum to the periphery of the blood agar plate

The microbiological analysis was repeated at 6 weeks, 3 months. Any signs of union were analysed clinically and radiologically at 3 months and 6 months.

Clinical analysis was done by assessing the absence of clinically detectable movement at fracture site, the range of movements of knee and ankle without pain, and the ability to bear the weight. Radiological assessment was done by assessing the anteroposterior and lateral radiograph views. Signs of union were determined by the presence of visible bridging callus across fracture. A semi structured questionnaire, filled by the investigator was used to collect data. Study variables included the factors like sex, age, mechanism of injury, site of tibial fracture, comminution, associated injuries, modality of surgical treatment and specific factors like diagnosis of the fracture by Gustilo and Anderson, and Tscherne classification, characteristics of the wound

as per Centres for Disease Control and prevention wound classification were assessed.^{4,5}

Outcome variables included

1. Presence or absence of infection (as determined by the blood agar culture growth) following lavage. A successful outcome was defined as the results of blood agar culture showing no or scanty growth of any microbiological organisms identified on the immediate post lavage wound culture compared to the pre lavage culture.

2. Presence or absence of signs of union in clinical and radiological assessment. Signs of union were defined as presence of callus in radiograph and clinical features of union.

The statistical data analysis was done by the calculation of the incidence of a successful outcome in each group and comparing with each other. All qualitative variables were analysed using proportions and the relative risk of infection in the group was analysed. The data were collected by a single investigator and analyses were performed using SPSS software.

Data was analyzed using SPSS Version 16.0. For the descriptive analysis of the quantitative variables, mean and standard deviation were calculated. Percentage distributions of the qualitative variables were also calculated. Statistical significance was defined at the 5% significance ($P < 0.05$) level for the analyses and for multiple regression analysis to minimize the risk of excluding potentially clinically important variables, higher P values were included regardless its univariate level of significance.

The patients who have been selected for the study were informed of the protocol, procedures, complications, expected advantages and disadvantages, and informed consent is duly obtained.

Instruments included were the pulsatile lavage machine, its associated tubings (autoclaved after each use), suction apparatus, and protective gear for the surgeon and covering for the wound to prevent environmental contamination. Culture swabs and bacterial colony count were arranged with the help of department of microbiology.⁶

RESULTS

The study included total of 39 persons who sustained Gustilo and Anderson type II/III fracture both bones leg. They were divided into two groups randomly, one group to undergo pulsatile flow lavage (18 persons) and a second group to undergo the continuous flow lavage (21 persons). In the study sample, the youngest person was 20 years old and the oldest 44 years old. Maximum

numbers of patients were in the 25-29 age group (38.5%). The mean age of the study sample was 32.8 ± 6.9 years. The age distribution of the study subjects was comparable in both the groups on chi square test. Males dominated the sample with 82.1% with a male to female ratio of 4.6:1. However gender distribution in the two groups was comparable on Chi square testing. Road traffic accidents ranked the highest in the mechanism of injury of the sample with 66.7%. Majority of the fracture patterns were of Gustilo and Anderson classification Type II (46.2%) and Tscherne grading Grade II (87.2%). Associated injuries other than the fracture were present in 33.3% cases. This included mostly head injuries and spinal injuries. Most of the subjects (48.7%) had a clean contaminated wound (CDC classification). Almost same number of persons underwent interlocking nail (46.2%) and external fixation (41%). Radiological signs of fracture union was present in 64.1% of the whole sample of the 18 subjects in the pulsatile lavage arm, 66.7% had radiological signs of union but it was only 61.9% among the continuous lavage group. However this difference was not statistically significant ($p = 0.757$). Of the total of 39 subjects, 15 (38.5%) had a successful outcome (immediate post lavage no/ scanty growth, who had moderate/heavy growth prelavage). The immediate post lavage success outcome (no/scanty growth) in those with moderate and heavy growth in blood agar culture was higher in pulsatile group (44.4%) than in continuous flow group (26.3%) which was statistically significant ($p < 0.00$). There were no persons with a heavy culture growth after 3 months in both the groups. Continuous flow group had more number of persons (95.2%) with no/scanty growth in blood agar culture after 3 months than in the pulsatile flow group (94.4%).

Gram stain of the total sample showed gram positive *Cocci* in most cases (69.2%). Most subjects in the total sample were infected with *Staphylococcus aureus* (51.28%).⁷

Factors affecting outcome

It was noted that most of the successful outcome were in the age group of 25-29 years (46.7%) and in the male gender 66.7%. The success outcome rate was 73.3% in those with Type II Gustilo Anderson fracture compared to Type III (26.7%). All persons with successful outcome had Tscherne grade II fracture. Also a clean or clean contaminated wound (CDC) classification had more chance for successful outcome (86.7%) than contaminated or dirty wounds. The factors that were statistically significant were analyzed using multivariate regression analysis. They were

- Gustilo and Anderson classification of fracture pattern
- Tscherne grading of fracture patte
- CDC wound classification
- Pre lavage blood agar culture growth

It was found that most important factor contributing to a negative outcome was heavy growth in blood agar

culture prior to lavage (multivariate regression analysis, $p=0.030$).

Table 2: Blood agar culture growth in both groups prior to and after lavage.

Blood Agar	Growth	Pre-lavage		Post-lavage		After 6 weeks		After 3 months		P*
		N	%	N	%	N	%	N	%	
Pulsatile	No/ Scanty growth	0	0	8	44.4	14	77.8	17	94.4	$\chi^2=44.795$; $p<0.001$
	Moderate growth	6	33.3	8	44.4	3	16.7	1	5.6	
	Heavy growth	12	66.7	2	11.1	1	5.6	-	-	
	Total	18	100.0	18	100.0	18	100.0	18	100.0	
Continuous Flow	No/ Scanty growth	2	9.5	7	33.3	15	71.4	20	95.2	$\chi^2=44.959$; $p<0.001$
	Moderate growth	7	33.3	10	47.6	5	23.8	1	4.8	
	Heavy growth	12	57.1	4	19.0	1	4.8	-	-	
	Total	21	100.0	21	100.0	21	100.0	21	100.0	

*P- Friedman test

Table 3: Logistic regression.

Variables	B	S.E.	Wald	df	Significance	Exp (B)
Gustilo and Anderson	0.540	1.001	0.291	1	0.590	1.715
Tscherne grading	19.173	17766.691	0.000	1	0.999	2.122E8
CDC wound classification	0.936	1.118	0.701	1	0.403	2.549
Pre lavage blood agar culture	2.384	1.096	4.729	1	0.030	10.847
Constant	-44.481	35533.382	0.000	1	0.999	0.000

DISCUSSION

This randomized control trial was undertaken to evaluate the efficacy of pulsatile lavage irrigation in reducing wound infection in patients with compound fractures of both bones of leg compared to those who underwent continuous flow debridement method and to study various factors that affects the wound infection.^{8,9}

The study included total of 39 persons who sustained Gustilo and Anderson type II/III fracture both bones leg. They were divided into two groups randomly to those who would undergo pulsatile flow lavage (18 persons) and those who would receive the continuous flow lavage (21 persons).

Males dominated the randomized control trial with 82.1% which was comparable with epidemiological data obtained from other studies.¹⁰ The male to female ratio was found to be 4.6:1. The youngest person was 20 years old and the oldest 44 years old. Maximum numbers of patients were in 25-29 age group (38.5%).

The mean age of 32.8 ± 6.9 years was younger than the mean age mentioned in other studies, where the maximum persons were in the age group of 40-55 years.¹¹ The decrease in mean age may be due to the restriction of higher age group in the study population and due to the male domination of the study population. This was significant from the fact that, in most

cases the mechanism of the injury was due to road traffic accident (66.7%). Associated injuries were present in 33.3% cases. This included mostly head injuries and spinal injuries. Majority of the fracture patterns were of Gustilo and Anderson classification Type II (46.2%) and Tscherne grading Grade II (87.2%). Most of the persons (48.7%) had a clean contaminated wound^{8,9} (CDC classification) while in another study by Gregory A. Mote, Scot Malay majority had contaminated wound (35.6%).¹¹⁻¹³ Almost same number of persons underwent interlocking nail (46.2%) and external fixation (41%). Fracture union was present in 64.1% cases. Among the 39 persons, 15 had a successful outcome implying that immediate post lavage blood agar culture showed no/scanty growth.

Analysis of outcome

It was found that even though pulsatile lavage (44.4%) had more success outcomes than the continuous flow (33.3%) method, the difference was not statistically significant (Chi-square test, $p=0.477$); indicating that absolute efficacy of pulsatile lavage cannot be claimed over continuous flow method. This may be due to the small size of study population. The persons who had radiological signs of union were comparable in both pulsatile flow group (66.7%) and continuous flow group (61.9%).

It is interesting to note that the success outcome in those with moderate and heavy growth in blood agar culture

was higher in pulsatile group (44.4%) than in continuous flow group (26.3%). There were no persons with a heavy culture growth after 3 month in both the groups. Continuous flow group had more number of persons (95.2%) with no/scanty growth in blood agar culture after 3 months than in the pulsatile flow group (94.4%). Most persons were infected with *Staphylococcus aureus*. Gram stain showed gram positive Cocci in most cases (69.2%).

Factors affecting outcome

The factors affecting outcome for the entire study population, irrespective of the type of lavage each person underwent, were analyzed by univariate analysis. It was noted that most of the successful outcome were in the age group of 25-29 years (46.7%).

Almost all persons who had successful outcomes (11 out of 15) were sustained with Gustilo and Anderson Type II fracture pattern cases (73.3%). The persons who had sustained Gustilo and Anderson Type III fracture had 6 times the chance to develop a negative outcome than Type II fracture. All persons with successful outcome had Tscherne grade II fracture.

Also a clean or clean contaminated wound (CDC classification) had more chance for successful outcome (86.7%) than contaminated or dirty wounds.^{14,15} A contaminated or dirty wound was 10 times more prone to a negative outcome than for a clean wound.

In the 24 failure outcomes 21 (87.5%) were having heavy growth in the pre lavage culture where as in the success outcome cases only 3 (20%) out of 15, were having a heavy growth. This observed difference was statistically significant (univariate analysis, $p < 0.001$). This implied that a heavy growth in pre lavage blood agar culture had 28 times chance to develop a negative outcome. Multivariate regression analysis done for statistically significant factors. They were

- Gustilo and Anderson classification of fracture pattern
- Tscherne Grading of fracture pattern.
- CDC wound classification
- Pre lavage blood agar culture growth

It was found that most important factor contributing to a negative outcome was heavy growth in blood agar culture prior to lavage (multivariate regression analysis $p = 0.030$).

CONCLUSION

The success outcome in the pulsatile lavage group (44.4%) which was significantly higher than in continuous flow group (26.3%; $p < 0.00$). In the study population (including both pulsatile and continuous flow group) heavy growth in pre-lavage blood agar culture

was the single most important factor that determines the persistence of infection in compound fracture of both bones of leg. The heavy growth in pre lavage blood agar culture had 28 times chance to develop a negative outcome than in a case of moderate or scanty growth. Low age group (25-29 years), Gustilo and Anderson type II, Tscherne grade II and clean or clean contaminated wounds (CDC classification) had more chances of positive outcome. Type of lavage did not affect the union of fracture because presence of radiological signs of union was comparable in pulsatile group (66.7%) and continuous flow group (61.9%).

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Conflict of interest: None declared

Ethical approval: The study was approved by the institutional ethics committee

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