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A Randomized Clinical Trial: The Efficacy of Hypochlorous Acid on Septic Traumatic Wound.

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Abstract
Background: Hypochlorous acid is a highly microbiocidal active agent against a broad spectrum of microorganisms. It achieved a marked reduction in the bacterial burden in a septic wound. This study **aimed** to evaluate the efficacy of Hypochlorous acid as a wound care agent in a septic traumatic wound. **Materials and Method:** **Design**: The current study used a randomized clinical trial to investigate the effectiveness of Hypochlorous acid as a wound care agent in a septic traumatic wound. **Setting**: trauma unit at Assiut university hospital was the setting of the study. **Subjects:** A random selection of 60 patients was done. Then a random distribution of the subjects to study group and control group, (30 subjects each) was done. **Methods**: The 30 subjects of the study group received Hypochlorous Acid for daily washing a septic wound for 3 to 5 minute, while the 30 subjects of the control group received Povidine Iodine and the results were compared. Bacterial count and culture were done before start washing, after one week, and two weeks in the two groups. **Results:** wound pain, odor, discharge and bacterial count were dramatically reduced by using as a disinfectant agent compared to the use of Povidine Iodine. **Conclusion:** Hypochlorous Acid appears to be inexpensive, easy to perform, painless and effective as a potent wound care dressing against a wide range of microorganisms. Hypochlorous Acid controls the tissue bacterial bio-burden without inhibiting the wound healing process, rapidly relieves pain and the area well prepared to skin flap or graft. **Recommendation:** The study recommended the use of Hypochlorous Acid as a potent wound care dressing. Further research is needed on a larger scale to validate the effectiveness of Hypochlorous acid as a wound care agent in a septic traumatic wound.
Keywords: Efficacy, Hypochlorous acid, Septic wound, Bacterial burden

1.Introduction

Acute wounds are wounds that heal within an expected time frame without any complications (1). Traumatic wounds are one type of acute wounds that account for about 20-25% of emergency department workload (2). According to the nature and mechanism of injury, traumatic wounds can vary from simple abrasion to soft tissue loss (3). Any traumatic wounds should be considered contaminated at presentation (4). And often predispose to infection, due to the presence of devitalized tissue, foreign bodies and bacteria, which may range from cellulites to deep myositis (5). Bio-film formation due to bacterial colonization is recognized to play a significant, detrimental role in the wound-healing process and progress to closure (6, 7). Wound is very rapidly colonized and ninety-five percent of acute wounds are infected with aerobic microorganisms (8). Wound being painful is due to bacterial adverse effects (9, 10).

A critical part of wound-bed preparation includes treating infection (11). And quantitative reduction of bacteria to a level that is treatable by the immune system, also pain and odor due to infection should be eliminated (12). Removal of bacteria and surface contaminants should consist of thorough wound-bed preparation and aggressive wound cleansing with a prepared non-cytotoxic wound cleanser to reduce bacterial bio-burden and infection rate and this allows the wound to move more rapidly from inflammation to proliferation, minimizing the risk of infection (11, 13,14,15).

If the wounds present with local clinical signs and symptoms of infection, topical administration of anti-microbial therapeutic agents is frequently adequate to address bio-burden in these wounds (16). Wound cleansing forms an integral part of the management of traumatic wounds, because bacteria do not typically survive in a clean, healthy wound (8). It applies to the application of f1uid to help removal of exudates, debris, slough and contaminants (17). Many cleansing and topical antimicrobial agents, such as Dakin solution (NaOCl), Hydrogen Peroxide (H2O2), Acetic Acid, and Povidine Iodine are known to be toxic to many of the cells involved in the wound-healing cascade and so impede wound healing (18,19,20,21,22).

Povidine iodine even at low concentrations has been shown to be toxic to granulocyte and monocyt (23) and results in decreased chemotaxis (24). 1t is also capable of suppressing lymphocyte functions (25). Hypochlorous acid (HOCl) is a non-cytotoxic and a highly active microbiocidal agent that is active against all bacterial, viral and fungal human pathogens (26). It has been used in acute wounds and has a positive impact on maintaining the wound environment and subsequently, supporting the healing process. Also, Hypochlorous acid reduces the pain and odor that is often associated with the wounds (27).

The objectives of wound management are to remove the tissue debris and to create optimum local conditions for

wound healing (28). And to reduce patient's pain, malodour, the frequency of dressing changes required the volume of exudates, the local signs of infection and to prevent deterioration of the wound (29).
Wound care is mainly a nursing job, that depends on observation, recording; and reporting the consistency, color, odor of any drainage, the type, extend and characteristics of the wound (30). The purposes of the wound dressing include cleaning a wound to removing any dirt and debris from the wound bed, preventing infection to prepare the wound for healing and protecting a clean wound from trauma so it can heal normally and notifying any signs of abnormal wound healing (31).
The nurse must follow the infection control protocol for keeping the wound free from infection, and the patient's environment should be free as possible from contamination. Closely monitor sign and symptoms of wound infection is an essential role of the nurse, if an infection develops culture and sensitivity test should be done to determine the organism and the most effective antibiotic and local antiseptic solution for that specific organism (32).When the nurse is changing a dressing, inappropriate facial expressions can alert the patient to problems with the wound or the nurse's ability to care for it. Winking of the noise by the nurse may convey disgust to the patient. A nurse should also be careful not to be focus on the wound to the extent that the patient is not treated as total person (33).

Significance of the study

Recent reports from doctors and nursing staff in the traumatic unit at Assiut university hospital and also from the patients pointed out to an increased incidence of wound infection that lead to long of hospital stay, increased hospital cost and nurses load which interfere with optimal care and increase patient disability. The number of patients with traumatic wound admitted to traumatic unit of Assiut University Hospital in the last year was 5000 case according to the Hospital statistical record (2013).

2.Patients and methods

2.1Aim of the study

This study aimed to evaluate the efficacy of Hypochlorous Acid (HOCl) compared to Povidine Iodine as a wound care agent in a septic traumatic wounds.

2.2Research Hypothesis

Septic traumatic wounds that were cleaned by Hypochlorous Acid (HOCl) will have fewer odors, exudates, heal faster and patients will have less pain than those whose wounds were cleaned with Povidine Iodine as a wound care agent.

2.3 Research Design:

The current study used a randomized clinical trial to investigate the effectiveness of Hypochlorous acid compared to Povidine Iodine as a wash therapy in treating acute infected traumatic wounds.

2.4 Setting:

This study was carried out in trauma unit at Assiut university hospital

2.5 Subjects:

Simple random sample of 60 patients who were admitted in trauma unit at Assiut University Hospital between May and December 2012,and willing to participate in the study were recruited. They were randomly assigned into two equal groups, study and control group, (30 patients each).

2.5.1 Inclusion criteria

The patients had been selected according to the following criteria:

1. Age more than 15 years and less than 45 years
2. Both sex
3. Conscious and alert
4. Acute traumatic wound

2.6 Tools of data collection

2.6.1 Tool 1. An interview questionnaire to illicit information about: patient's age, gender, occupation, size, site and condition of the trauma, medical data as laboratory investigation...

2.6.2 Tool II: **Open wound Assessment using an observation chart:**

It was developed by the researcher for initial wound assessment such as wound bed, surrounding skin exudates, color, exudates' amount, and odor, frequency of wound pain, and condition of the dressing.

2.6.3 Tool III: Evaluation sheet:

2.6.3.1 Part one: It was developed by the researcher for evaluating signs and symptoms of infection such as pus, pyrexia, level and frequency of pain, color, amount and odor of exudates. It was used at the initial assessment of the wound, at every dressing, at the 7^{th} day and at the end of study (14^{th} day).

2.6.3.2 Part Two:. Physiological Measurement was assessed using a sterile swab that was pressed laterally on the wound to express underlying tissue fluid and exudates.It was taken for semi -quantitative microbiology at the start and the end of the treatment regimens.

3. Methods

3.1 Administrative approval: An official was forwarded from the dean of the Faculty of Nursing, Assiut University explaining the aim of the study, and requesting a permission to conduct the study. A written approval was obtained from the director of trauma department to carry out the study. The study was approved by an institutional ethics committee.

3.2 Tools development: The study tools were developed by the researchers after extensive review of the relevant literature.

3.4 Validity: This tool was tested for content validity by five experts in the field of nursing and surgical specialists. Modifications were done accordingly then the tool was designed in its final format.

3.5 Ethical consideration: Consent: The study was approved by an institutional ethics committee. Informed consent was obtained from patients to participate in the study. The researchers initially introduced themselves to all potential subjects and they were assured that the collected data were absolutely confidential. They were informed that participation is voluntary and they can withdraw at any time of the study.

3.6 Pilot study: A pilot study was conducted before starting data collection on (3) patients who was included in the sample to test the clarity, and applicability of the tool and to estimate the time required to fill the sheet. Modifications were done as needed.

4. Data collection:

The data collection was done in the following phases:

4.1 Assessment phase:

The researcher interviewed the patients individually and gets their oral consent to participate and they answered the questions in the interview questionnaire. Initial assessment of the wound condition was done and recorded.

4.2 Implementation phase:

Hypochlorous acid was used as an antiseptic wash solution for the study group, while Povidine iodine was used for the control group. A standardized sheet recording patient's details included, age, sex, location of lesion, clinical history, and wound assessment, special investigations, clinical response were recorded and reported. Also, the wound condition was recorded by a serial of photographs and special investigations before, during, and after completion of the treatment.

Pain: All wounds were assessed by the researcher daily in accordance with standard of care. At each visit, the degree of pain was assessed using the developed questionnaire, patients were asked to report their pain as it happens in the following forms: none, only during dressing, intermittent, or continuous

Exudates: A sterile swab was taken from the exudates for quantitative microbiology at the start, 7^{th}, and 14th day of the treatment regimens, odor was assessed and recorded as none, only when dressing was removed, or before and after dressing was removed. The nature and amount of exudates were also assessed and recorded as high, when the dressing was soaked with discharge and the patient need twice daily dressing, moderate, when the patient needed once daily dressing , or low exudates, when dressing was changed every other day.

Color: Wound bed was assessed as healthy (red in color and no dead tissue) or non-healthy (white or black color and there is necrotic tissue) granulation tissue . Routine blood samples were taken on admission, 7^{th}, 14^{th} days for a biochemical screen and full blood count

Pyrexia: Systemic antibacterial chemotherapy was routinely restricted to the patients when their temperature more than 38 C and depended on the culture and sensitivity results.

4.3 Procedure: Patients received either conventional therapy (control group) or treatment of the wound with Hypochlorous Acid (study group).

The study group: remove any old dressing from the wound, then gently scrub the wound by using sponge soaked with normal saline (Nacl 0.9%) to remove any debris and excessive wound drainage and, then irrigate the wound with Hypochlorous acid in a concentration by adding Nacl 0.5% to HCL 51.5% at ratio 9 :1 and for 3-5 minutes.

Control group: The same procedure was done for control group except, use of Povidine iodine instead of Hypochlorous acid as a wash therapy.

Changing dressing was done daily, once daily, or once every other day according to the amount of exudates for both groups.

4.4 Follow up: The follow-up of the two groups was done in trauma unit, during each assessment, standard parameters of wound pain, odor level, and color and amount of exudates were evaluated. After clinical improvement of the wound, the target lesion was operatively reconstructed by flap or graft.

5.Data Analysis

The data obtained were reviewed, prepared for computer entry, coded, analyzed and tabulated. Descriptive statistics (i.e., frequencies, percentage, mean standard deviation, etc) was done using computer program SPSS version (17). Chi-square and T-test, test used to compare differences in the distribution of frequencies among different groups.

6. Results

6.1(Table 1). Illustrated that, this study was performed on 60 patients with traumatic septic wound divided equally to control and study group, their mean ages ranged between 32.47±10 and 32.17±11.2 respectively. There were 47 men and 13 women. Most of the wounds in both groups were at the lower limb.

Wound was ready for surgical reconstruction in 90% of the study group (using Hypochlorous acid HOCl) compared to none in control group within 2 weeks, and the rest of the study group (10 %) were ready for coverage within 3 weeks compared to 6.67% in the control group. However, the majorities of the control group (93.33%) was slow in healing and were ready after more than 4 weeks.

7.2(Table 2) and (figure 8). Showed that, at the beginning of the study, 63% and 67% of the study group and control group successively, complained from continuous pain. However, the pain was decreased among the entire study group after 7 days compared to 33.3% and 20% successively, after 7 days and even after 14 days. The differences were statistically significant (P value 0.004 Fig 8.)

Regarding the wound odor, Table 2 showed that 87% of the study and control group at the beginning of the assessment had offensive odor that the researcher smelled before and after dressing was removed. As for the study group who were treated with HOCl, the odor was reduced to nil within 7 days compared to 70% , 50% of the control group who still had odor at the 7^{th} and 14^{th} day's dressing successively, (P value 0.001)

Concerning exudates, the table illustrated that, at the beginning of the study, the majority of the patients had purulent exudates (80%, 83%) among the study and control group. However, at the 7^{th} day none of the study group had purulent exudates compared to 57% at the 7^{th} day and 50% at the 14^{th} day of the control group. Sanguineous exudates were observed among 97% of study group compared to 10% of the control group. Also, all wounds of the study group were Serous at the 14^{th} day compared to only 10% of the control group. The differences between the study group and control group were statistically significant. (P value 0.004)

There was a significant difference between control and study groups in the volume of exudates where, the amount of exudates was high, among 70% of wounds in both groups at the start of this research. This percentage had changed to zero among the study group compared to 57%, 36.7% for the control group at the 7^{th} and 14^{th} days respectively. The differences were statistically significant (p value 0.005)

There were 5 different types of microorganisms in this study according to the culture results Klebsella, Proteus, NIF, MRSA, and Psydomonus. There were a statistically significance decrease in quantitative reduction of micro-organisms between using Hypochlorous acid and Povidine iodine as a wash therapy in treating infected traumatic wounds (P value 0.0001, Fig 9)

7. Discussion

Despite a growing enthusiasm in the antiseptic products in the last few years, in the field of treatment of infected wounds, there is no universal agreement on what product is the best to wash infected traumatic wounds. Therefore the current study investigated whether washing infected wounds with HOCl would bring an improvement in patients with infected traumatic wounds more than the conventional method of using to Povidine iodine. Infection of traumatic wounds by MRSA, Pseudomonas, Proteus, NIF, and Klebsella is problematic because these pathogens can form a biofilm that can often go unchecked, leading to an unrecognized infection. This infection compromise normal wound healing and becomes a major obstacle for wound closure (34, 35, 36, and 37). Controlling the bacterial bioburden in traumatic wounds has been very difficult. If the physician cannot control the infection in these traumatic wounds, the patient may become further compromised by additional devastating tissue damage, bacteremia, sepsis or deeper wound infections. Topical antiseptics have been the method of choice, and have been used in preference to topical antibiotics because of concerns about the development of bacterial resistance. but still do not fully provide effective alternatives or significant improvement due to, the cytotoxic effects of these agents on the host, dermal and epidermal cells that may affect the wound healing process (38).

The search for a safe and effective topical antiseptic remains the biggest challenge. Povidine iodine is the most commonly used antiseptic dressing of traumatic wounds but the use of it has decreased due to its cytotoxic effect to cells that essential for wound repair, and due to tissue damage of fibroblasts in the wounds, which are required for healing and epithelization (21,37,38,39). However, there have been few controlled studies of the efficacy of the Povidine iodine and other antiseptics, such as ionized silver, alcohol, acetic acid, or hydrogen peroxide (38,39). It is reported that HOCl can kill bacteria without cytotoxic effect to human cells (40,41,42,43,44). So it could be an alternative to Povidine iodine , as it has shown antimicrobial efficacy, against many pathogens and even against antibiotic-resistant bacteria, such as MRSA without inducing toxicity (38,39,44).The result of this study supports the previous studies that, Hypochlorous acid is highly effective against a broad range of microorganisms including MRSA, Pseudomonas, Proteus, NIF, and Klebsella compare to use Povidine iodine as a washing therapy in treating infected traumatic wounds and this is evidenced by no further necrosis, rapid formation of healthy granulation tissue and by quantitative microbacterial results. Randell (2012), reported that

HOCl is a key agent in promoting healing for a wide variety of wound types (45).The present study revealed that HOCL is highly effective in treating wound infection, and this enables the body's natural healing process. Also, the findings f the current study proved that the traumatic wounds are surgically closed sooner after using of HOCl as a washing therapy when compared to Povidine iodine.

A tender painful wound is an adverse effect of bacterial infection (34,35). Selkon et al.,(2006) & Randell (2012) ,supported the study findings where pain has decreased and totally disappeared after 14 days of using HOCL compared to the control group who were using Povidine iodine(44,45).. Pain was, present in all patients upon starting the study, completely ceased to exist in all patients of Hypochlorous acid group compare to 16.6% of the control group, and also the researcher observed that HOCl has been well tolerated throughout the course of therapy. These findings contribute to HOCl which has an excellent effect in reducing pain of the wound

As for the wound odor, the findings from the present study support a previously accepted hypothesis that, a significant odor was completely eliminated in all patients of HOCl group, even in those who were not ready for coverage completely, compared to patients of control group at the end of study. Similarly, Selkon et al.,(2006) reported that HOCl breaks the structural bonds by reacting with proteins, fatty acids, and DNA and this leads to soften the wound surface eschar, necrotic tissue, and biofilm on a painful granulation tissue. (44). And this concomitant with the current result where, the researcher observed that HOCl softens, cleans, and removes the necrotic tissue and biofilm from acute infected traumatic wounds at the end of this study.

As regard exudates amount, the current findings showed that about three quarters of wounds were infected with high amount of exudates at the beginning of the study which dropped to nil after 14 days of using HOCL among the study group, compared to 36.7% among the control group. This finding was supported by McDonnell G, Russell AD, (1999) and Ovington (2004). Who reported that a clean wound should show signs of healing and improvement within two to four weeks (46,47). Likewise, Selkon and Cameron (2001) reported that Hypochlorous acid reduce the bacterial flora of the ulcers after the two days (48).

Concerning exudates color, the results of the wound observation in the current study revealed that the majority of the wounds in the study group and control group were purulent at the initial assessment of the wound. This color improved to be Serous among almost all the study group after 7 days and among all of them after 14 days, compared to more than half of the control group after 7 days and half of them after 14 days. This finding means that there was marked quantitative reduction of bacteria when using Hypochlorous acid compared to Povidine iodine. This finding was supported by McDonnell G, Russell AD, (1999) and Ovington (2004).

8. Conclusions

Hypochlorous acid (HOCl) is an effective; easy to perform, comfortable, inexpensive and safe in cleansing (treating) infected acute traumatic wounds and allows for earlier surgical closure and hospital discharge. HOCl controls the tissue bacterial bioburden without inhibiting the wound healing process rapidly relieves pain and the area becomes well prepared for skin flap or graft. The photographs were an evidence to support the effectiveness of HOCL in accelerating wound healing process.

9. Recommendations:

Further studies to confirm the effect of HOCl with larger number of patients is needed.

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Table (1): Subject characteristic of socio-demographic characteristics for control and study groups

Variable	Group			
	Control (n=30)		Study (n=30)	
	No.	%	No.	%
1. Age (years):				
▪ 15-25	10	33.33	10	33.3
▪ 26 – 35	11	36.67	10	33.3
▪ 36-45	9	30	10	33.3
Mean + SD	32.47 +10.44		32.17+11.27	
2. Gender:				
▪ Male	24	80.00	23	76.67
▪ Female	6	20.00	7	23.33
3. Wound site:				
▪ Upper limb	1	3.33	4	13.33
▪ Lower limb	25	83.33	18	60.00
▪ Sacral	3	10.00	4	13.33
▪ Abdomen	1	3.33	4	13.33
4.Wound ready for flab or graft (healthy granulation tissue) after				
▪ 2 wks	0	0	27	90
▪ 3 wks	2	6.66	3	10
▪ >4 wks	28	93.33	0	0
4. HGB: **Mean + SD**	10.13+1.67		9.23+1.77	
5. PT **Mean + SD**	13.01+0.55		12.52+0.82	

Table (2): Frequency and percentage distribution of the sample according to wound assessment among control and study groups

Wound assessment	Control group(n=30)						Study group(n=30)						P.value
	0 day		7th day		14th day		0 day		7th day		14th day		
	No	%	no	%	no	%	No	%	No	%	No	%	
Exudate (colour)													
- Serous	0	0	0	0	3	10	0	0	1	3	30	100	0.004
- Serosanguinous	0	0	3	10	1	3	1	3	29	97	0	0	**
- Sanguinous	5	17	10	33	11	37	5	17	0	0	0	0	
purulent	25	83	17	57	15	50	24	80	0	0	0	0	
Exudate (amount)													
- low	0	0	1	3	9	30	3	10	27	90	30	100	0.005
- moderate	9	30	12	40	10	33.3	6	20	3	10	0	0	**
- high	21	70	17	57	11	36.7	21	70	0	0	0	0	
Odour:													
• none	0	0	0	0	4	13.3	0	0	25	83	30	100	0.001
• -only when dressing removed	4	13	9	30	11	36.6	4	13	5	17	0	0	**
• (before and after dressing removed)	26	87	21	70	15	50	26	87	0	0	0	0	
Wound pain (frequency)													
- None	0	0	3	10	5	16.6	0	0	20	66.6	30	100	0.004
- only at dressing	3	10	7	23.3	7	23.3	5	17	5	16.6	0	0	**
- Intermittent	7	23	10	33.3	12	40	6	20	5	16.6	0	0	
- continuous	20	67	10	33.3	6	20	19	63	0	0	0	0	

Fig 2.After 7 days of using HOCl

Fig 1 Male patient has unhealthy granulation tissue at Lt.cubital fossa at the start of study.

Fig 2.After 15 days of using HOCl

Fig 3 A

Fig 3 B

Fig 3 C

Fig 3 D

Fig 3.A, B, C, & D Male patient 35 years old, show infected traumatic wound at the start of the study

Fig 4.Within 2 weeks of using HOCL

Before application of HOCl

One week after dressing by HOCl

2 weeks after dressing by HOC

After three weeks,patient flaping

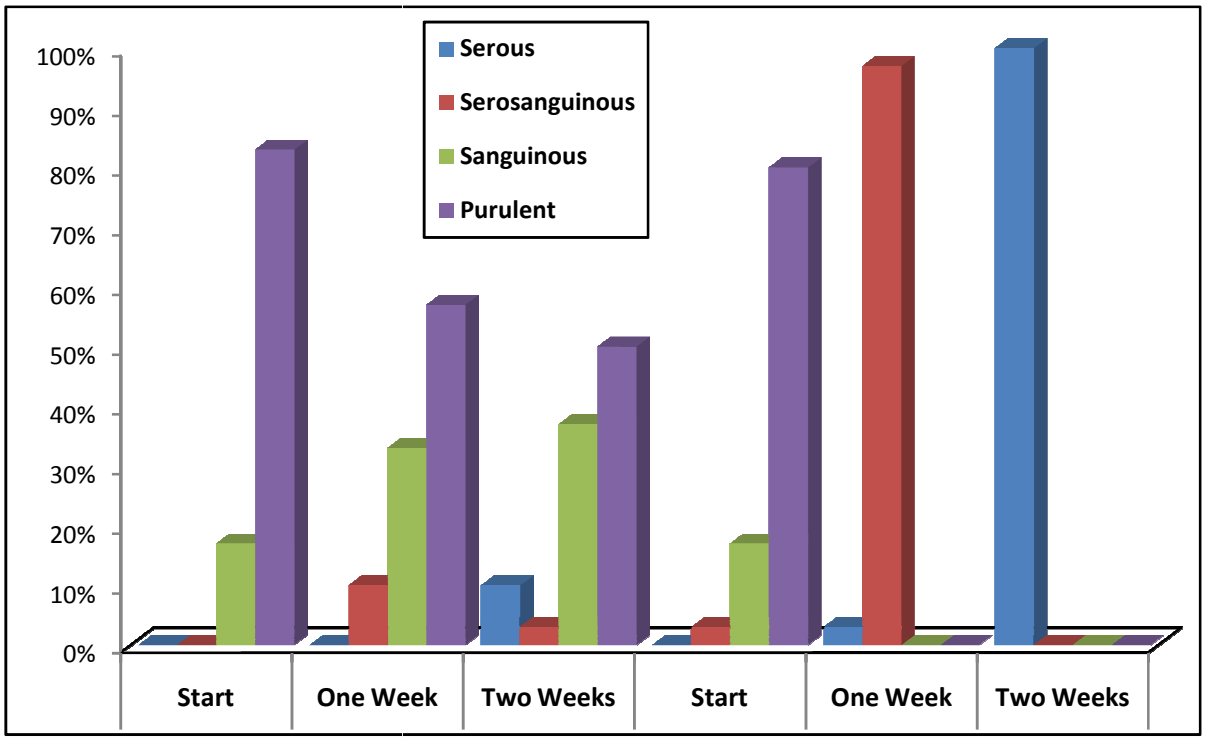

Fig. 5: Distribution of the sample according to the Colour of Exudates

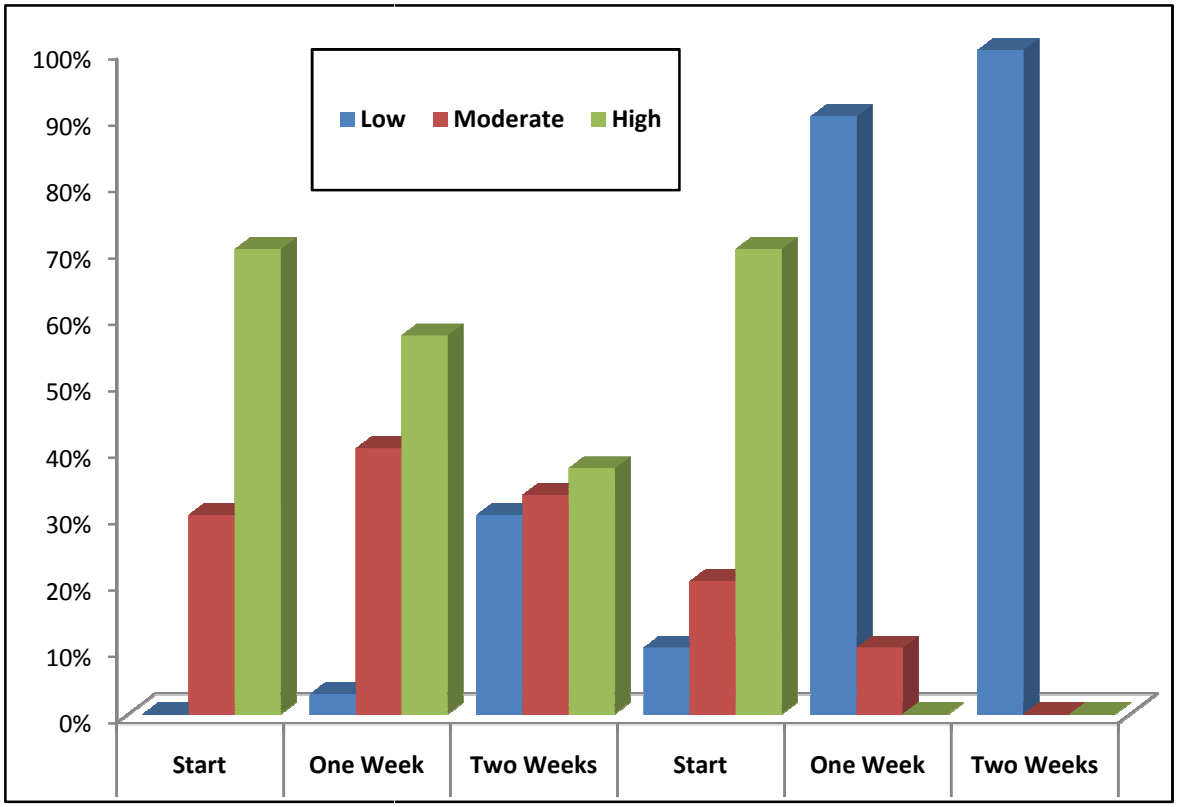

Fig. 6: Distribution of the sample according to the Amount of Exudates

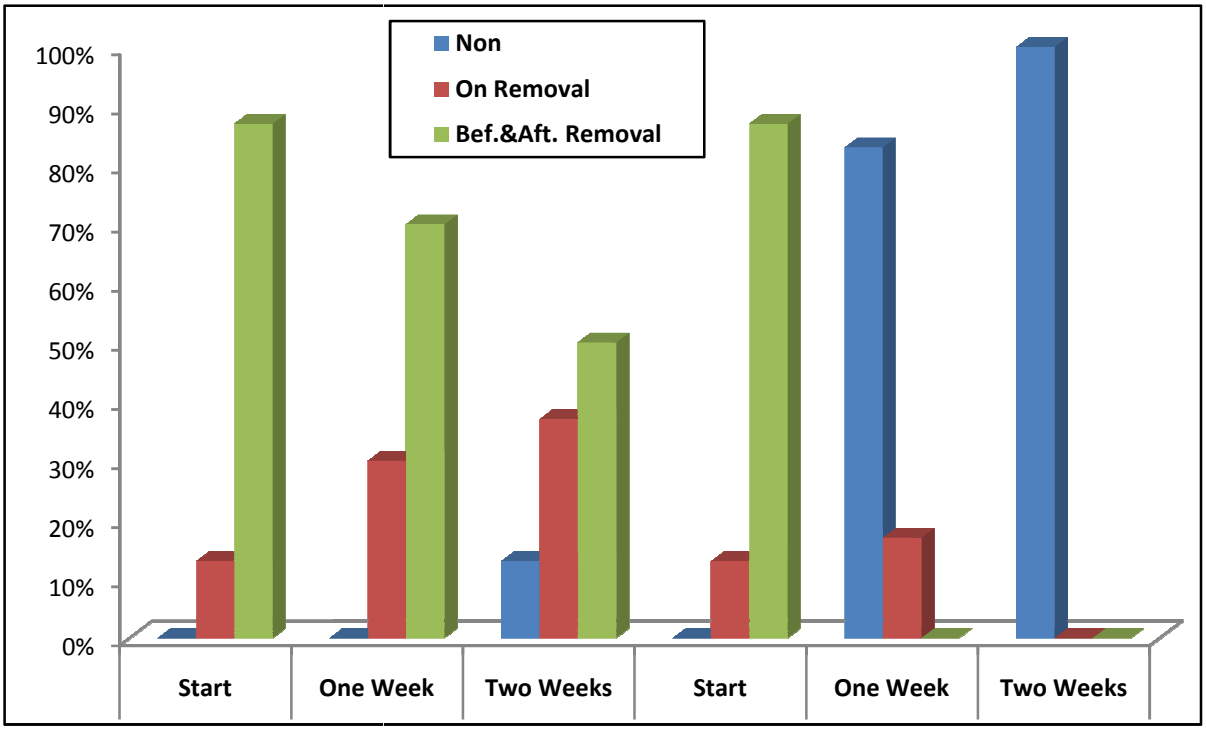

Fig. 7: Distribution of the sample according to Wound Odour

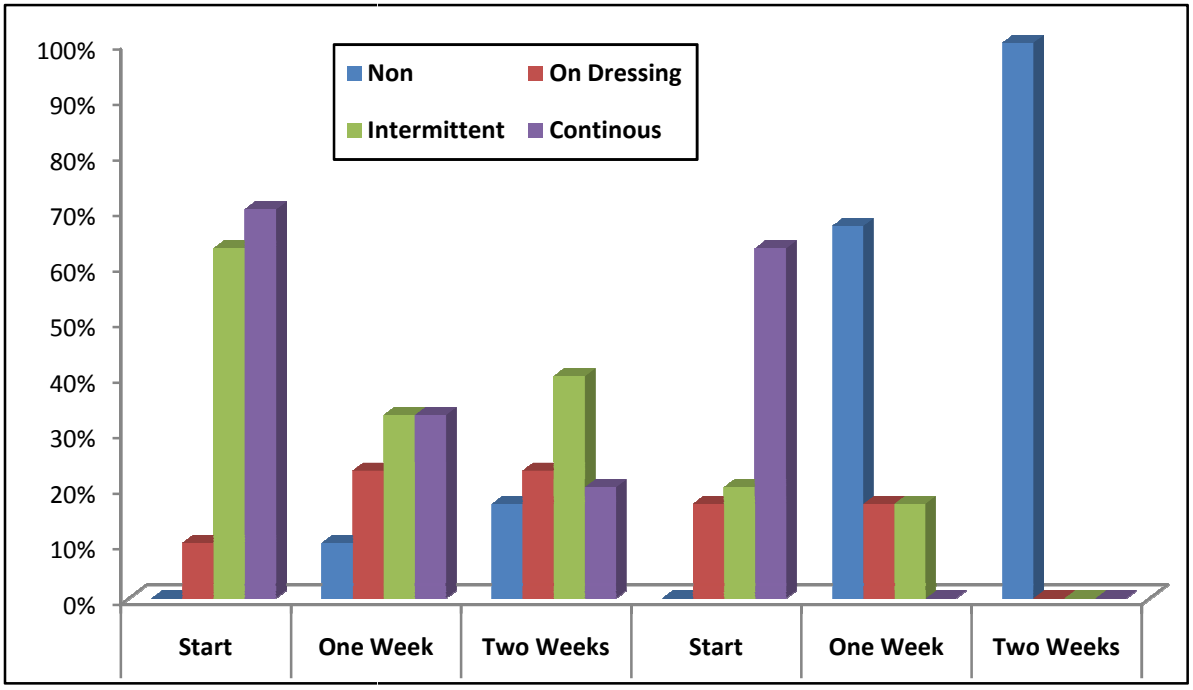

Fig. 8: Distribution of the sample according to Wound Pain

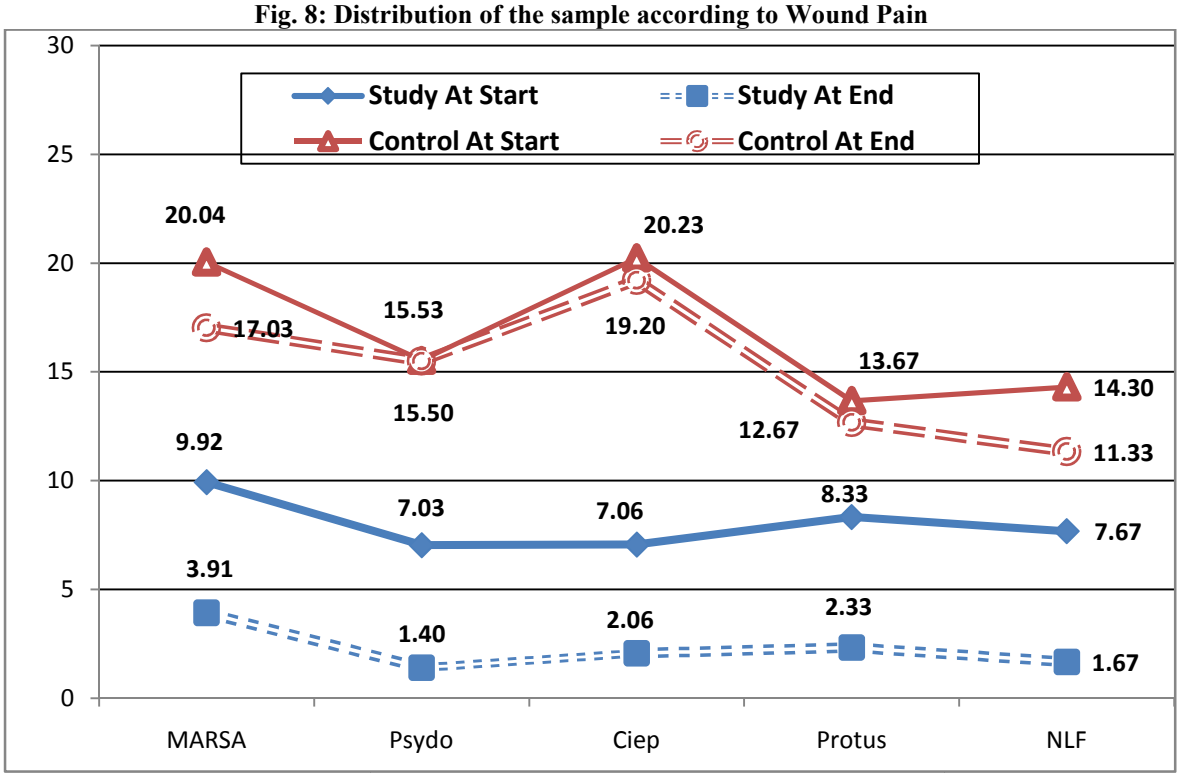

Fig. 9: Microorganism means scores in both groups at the start and end of the study.

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