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Research Article

Comparison of 2% Chlorhexidine and 70% Alcohol Swab Versus 10% Povidone- Iodine Solution in Preventing Peritoneal Dialysis Exit Site Infection

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Abstract

Background: Peritoneal Dialysis (PD) utilization increases gradually due to increase of patient's awareness for different types of Renal Replacement Therapy (RRT). Hence, in order to be successful with PD program, we need to build strong strategies to improve patients' quality of care. One of the risks associated with PD is the Exit-Site-Infection (ESI).

Objectives: This study aims to determine the potential effect of the application of 2% chlorhexidine swab at the catheter exit site in preventing ESIs compared to 10% Povidone-iodine for adults' patients who are on PD.

Methods: This is an experimental study where the newly starting patients on PD were randomly allocated to 2% Chlorhexidine & 70% Alcohol Swab or 10% Povidone-iodine solution. Patients were recruited over a one-year period and followed up for an average of nine months.

Results: 53 Participants with mean (SD) age of 47 (24 years), male 21 (53) aged 53.5 (23.2) and female32 (53) aged42.6 (24.3). Randomization end up with 51.9% used chlorhexidine swab and 48.1%used Iodine. 6-patients developed infection with total of 12 episodes, of which 4-cases were on 10% Povidone-iodine and 2-cases were on swab Chlorhexidine 2%. During the study period, skin-allergy occurred in9-patients using 2%-chlorhexidine. The estimated cost of exit site care for Iodine group was ($779.3) per nine months, while it only costs around ($571.5) with chlorhexidine group. The time utilized for exit site dressing with Iodine was 10 mints when compared with only 3 mints for chlorhexidine.

Conclusion: The 2% Chlorhexidine and 70% Alcohol swab are efficient for routine exit site care and reduces the risk of infections. It is a cost-effective and saves time. Additional studies with larger number of participants are needed to support these finding.

Keywords: Peritoneal dialysis; exit site, infection, peritonitis, 2% chlorhexidine; 10% Povidone-iodine; end stage kidney disease; renal replacement therapy.

Introduction

Almost 40,000 persons aged 40 years or more were screened for Chronic Kidney Disease (CKD) in a preliminary survey performed in 2009 throughout Oman(1, 2). Of the individuals screened, 0.9% had severe renal failure, with an estimated Glomerular Filtration (eGFR) rate of less than 30 ml/min/1.73 m^2; 9% had moderate renal failure with (eGFR) between 30 and 59 ml/min/1.73 m^2; and 29% had mild renal failure with eGFR of 60 to 90 ml/min/1.73 m^2. The incidence of patients with kidney disease in Oman who received renal replacement therapy (RRT) during 1983 was very low 21 Per Million Populations (PMP) and has been gradually increasing (75 PMP in 2001 and 120 PMP in 2013) [1]. The prevalence of patients with End-Stage Kidney Disease (ESKD) on RRT in 1983 was 49, which increased to 916 in 2001 and reached 2386 in 2013. By 31 December 2013, there were 2386 patients alive and on RRT, of whom 1080 were living with a functioning kidney transplant (45.3%), 1206 were receiving hemodialysis (50.5%) and 100 were undergoing peritoneal dialysis (4.2%) [1,2].

Peritoneal Dialysis (PD) is a readily available and simple method for selective filtration of excess water, clearance of uremic toxins and electrolytes balance. It has been reported to promote improved well-being and greater personal freedom than hemodialysis through less restrictive life-style changes. It has also been argued that PD should be offered to all appropriate ESKD patients [3,4] and it's a good option for motivated and independent patients [5].

In the Sultanate, the number of patients on PD is progressively but gradually increasing due to an increase in the load on hemodialysis and to the increase of patient's awareness for of different types of RRT. Hence, in order to be successful with our PD program, we need to build strong strategies to improve patients' quality of care. It can be initiated by adequate pre-dialysis care and achieved by proper monitoring of PD quality performance, training and re-training of

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staff and patients, implementation of international PD guidelines and by medical research and statistical studies to evaluate and improve the provided services. The most common problem of PD, that effects PD quality, is infection, which usually increases the rates of morbidity, mortality and the dropout (transfer to hemodialysis and death) and may leads to failure of providing PD services.

Peritoneal dialysis patients require a Tenckhoff catheter to be inserted into the peritoneal cavity via the abdomen abdominal wall to initiate this treatment. One of the risks associated with PD catheter implantation is Exit Site Infection (ESI) [6,7]. ESI is a significant contributing factor to high mortality rates and poor treatment outcomes in the PD population [8]. Inappropriately treated ESI can develop into a tunnel infection and may progress to peritonitis [9].

Prevention of infection is considered an essential tool for the successful maintenance of PD. Strategies to prevent or reduce the risk of infection are reported to include rigorous exit-site care, catheter care and meticulous attention to the use of a clean no-touch technique for dialysis exchanges. In addition to these strategies, other methods reported to prevent infection include reducing the buildup of bio film on catheters and treatment of nasal Staphylococcus aureus [6]. In many cases, this means increased patient care hours, hospitalization and in certain cases catheter removal and modality transfer. Accordingly, the development of superior infection prevention strategies is integral to the long-term success of a PD treatment [10]. For a PD program to be successful, close attention must be paid to the prevention of PD-related infection [11].

This study aims to determine the potential effectiveness of the application of 2% chlorhexidine swab at the catheter exit site in preventing exit site infection and peritonitis compared with 10% Povidone-iodine for adults' patients who are on PD at the Royal Hospital for a period of nine months starting November 2017 to July 2018.

Methods

The study examined the effectiveness of 2% chlorhexidine +70% Alcohol swab versus 10% povidone- iodine solution in preventing infection in PD catheter exit site. The research was conducted at the Royal Hospital, Muscat, using a quantitative non-blinded randomized control experimental design to examine the cause-and-effect relationship between the variables. This prospective clinical trial involved randomization of patients into two groups (1:1 ratio) by block randomization [12], with randomly mixed block sizes and the allocator hide the block size from the executer. Patients were recruited over a one-year period and followed up for an average of nine months. Exclusion criteria include PD patients who were planned to follow up in other hospitals.

Ethical approval for this research topic study was obtained from research committee at the Royal Hospital, MESRC 81/2016. The information about the research study and its purpose i was written and explained in the consent.

Informed consent was obtained from the all participants who were involved in this study. On top of the consent, there was brief explanation about the purpose and aim of the study. The participant requested to sign consent which instructs them to continue if agrees to be involved.

The researchers collected online recorded for all adult ESKD patients underwent PD catheter insertion and patients on peritoneal dialysis PD. The various demography and clinical data are collected prospectively via computerized system called AL-Shifa. The participants were contacted and met or full information if they want to participate in the study assuring complete confidentiality. Therefore, during their clinic visit they signed the consent.

All participants were treated fairly and the consent of this study was distributed at the same time and same period for completion. The participants were informed that the outcomes of this study will be published but their identity will be kept confidential and anonymous, where their name will not be disclosed to anyone outside the party. The participants were informed that there will be no risk for them in completion of the study; however, there might be no direct benefits and withdrawal from this study is permitted at any time.

All patients had standardized training on PD catheter exit site care. This was introduced by practical training and written instructions in Arabic and English languages, which helped in avoiding bias among different educational background of PD caregivers.

Full training was provided to all participants, which included exit site care using the antiseptics (2% chlorhexidine or 10 % povidone -iodine solution,) and health education of how to take care for of catheter exit site. Specifically, these include preparation of items needed for dressing and practical methods of applying dressing is to (exposure of the site, aseptic hand washing, cleaning the site proposed with antiseptic and drying the site carefully before applying Mupirocin ointment spot and cover the site with Merope or Tagaderm dressing). Participants were followed up regularly every four to six weeks at the PD clinic. During their follow up visits, we observed the site for patency and any signs and symptoms of inflammation and routine site swab was sent for microscopy and culture and sensitivity (c/s).

During the period of nine months, all participants were assessed for exit site status. This assessment included category of the site if perfect or infected, color of the exit site and surrounding skin, presence of scab or crust, pain or swelling over the exit site, drainage and granulation. Collected PD effluent fluid was examined for gram stain, Polymorphonuclear leukocytes count and c/s for bacterial or yeast growth.

All information recorded at exit site observation chart, using peritoneal dialysis catheter exit site classification Guide [13]. Serum albumin and WBC counts and differential were measured on each visit. All information recorded on excel sheet for nine months period started from November 2017 to July 2018.

Results

A 53 recruited PD patients were randomized into chlorhexidine (treatment) group (n=27, 51.9%) and iodine (control) group (n=26, 48.1%).There were 21 males with a mean age of 53.5±23.2 and 32 females with a mean age of 42.6±24.3, as shown in figure 1. The majorly to participants age group was between 41-65 years with percentage of 40.7%, figure 2 gives the details of age categories percentage of all participants. The body mass index (kg/m2) of the study participants was 25.6±8. A total of 24 (45.3%) patients have diabetic mellitus, 48 (90.5%) have hypertension and 25 (47.1%)

suffer from cardiac diseases, as shown in figure 3. Furthermore, 10 patients (19%) were on Continues Ambulatory Peritoneal Dialysis (CAPD) and 43 (81%) on Automated Peritoneal Dialysis (APD). Table 1 shows the summary of the demographic characteristics of the studied participants.

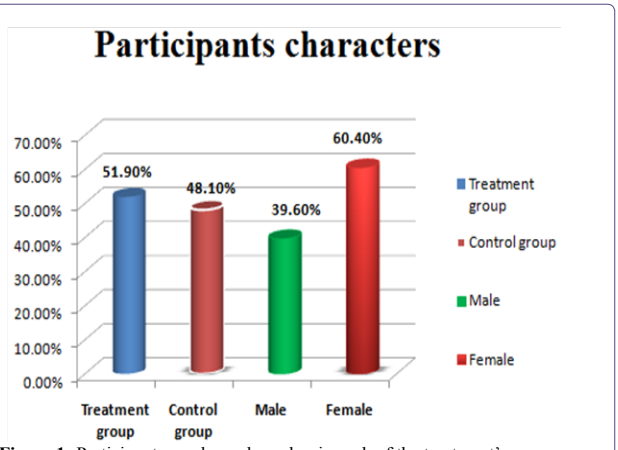

Figure 1: Participants gender and number in each of the treatment's groups.

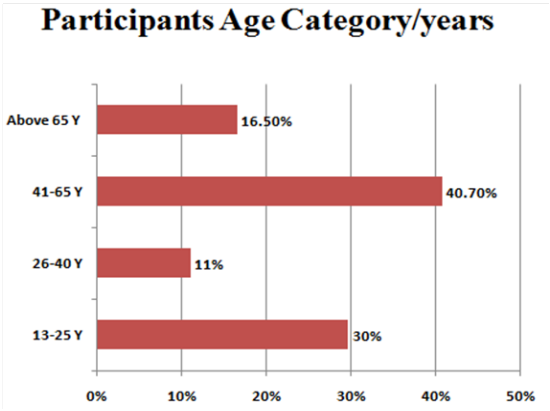

Figure 2: Participants Age Category in years for the participants.

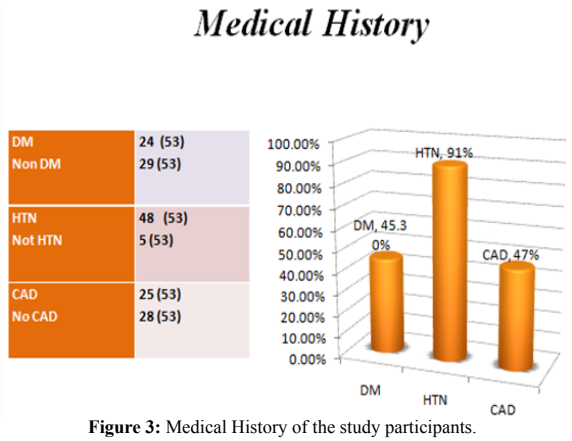

Figure 3: Medical History of the study participants.

Variables	All	Chlorhexidine Swab 2% +70% Alcohol	Povidone Iodine Solution	p
Total	53	27	26	
Gender				
Male	21 (53)	13 (27)	8 (26)	1.0
Female	32 (53)	14 (27)	18 (26)	
Mean age (years)	47 (24)	48.8 (26.8)	45.2 (21.5)	0.7
Mean height (cm)	155.4 (12.6)	156.1 (13.7)	154.6 (11.8)	0.8
Mean weight (kg)	61.4 (22.1)	58.3 (17.1)	64.7 (26.8)	0.5
Mean body mass index	25.6 (8)	23.8 (6)	27.5 (9.6)	0.2
Mobility Status				
1. Mobile	52 (53)	26 (27)	26 (26)	0.8
2. Immobile	1 (53)	1 (27)		
DM	24 (53)	16 (27)	8 (26)	0.9
Non DM	29 (53)	11 (27)	18 (26)	
Hypertensive	48 (53)	26 (27)	22 (26)	0.5
Not hypertensive	5 (53)	1 (27)	4 (26)	
Coronary artery disease	25 (53)	13 (27)	12 (26)	0.49
No coronary artery disease	28 (53)	14 (27)	14 (26)	
Had kidney transplant	4 (53)	3 (27)	1 (26)	0.8
No transplanted	49(53)	13 (27)	12 (26)	
PD Modality				
1. CAPD	10 (53)	6 (27)	4 (26)	0.5
2. APD	43 (53)	21 (27)	22 (26)	

Table 1: Shows the various demography and clinical data of the study participants.

Reviewing the social, education and environment characters for of the participants: showed 32 patients (60.4%) were living in Muscat, the capital area and 21 (39.6%) were living out-side Muscat. A total of 40 patients (75.5%) used sea desalination household as a source for of water supply and 13 (24.5%) used desalination of well ground water, as shown in figure 4.

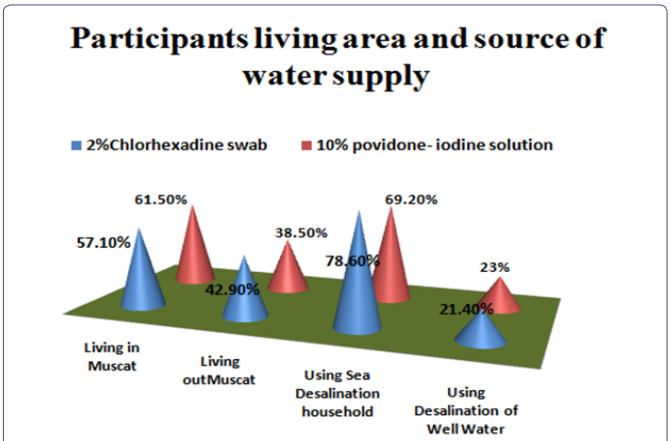

Figure 4: Participants living area and source of water supply.

Out of 53, 24 patients manage the dialysis by themselves and 29 patients needed assistance. One bedridden and 52 patients were

mobile, but 6 patients used walking assistances. Education level for PD caregivers: 37 (70%) had completed higher study while 16 (30%) had primary education, as shown in figure 5. A total of 14 (26%) of participants were students, 13 (24.5%) female participants were housewife, 14 patients were retired, 8 had jobs and 4 had no jobs, as shown in figures 6.

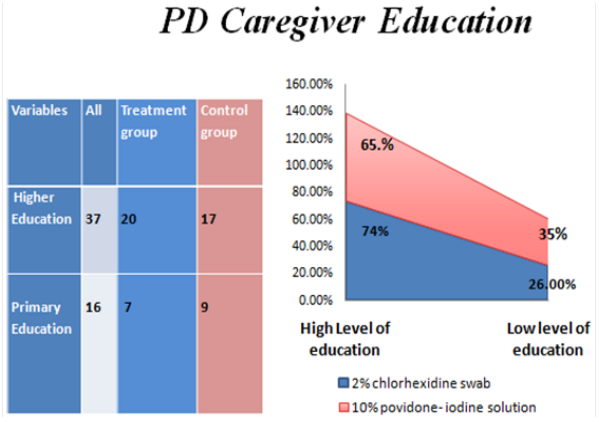

Figure 5: PD Caregiver Education level of relatives of patients on the study.

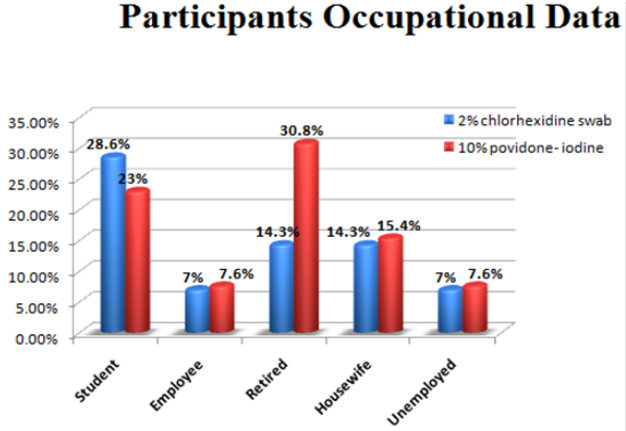

Figure 6: Participants occupational data.

During the period of nine months, all participants were assessed for exit site status. A total of 12 (22.6%) episodes of exit site infection developed for 6 (53) patients during the whole study period, 4 (26) from iodine-treated group and 2 (27) from chlorhexidine-treated group, as shown in graph 7. None of the 53 participants had history of positive nasal Methicillin-Resistant Staphylococcus (MRSA). In the first and fifth months of the study, 51 (96%) patients had perfect exit site. whereas There were 2 episodes (3.7%) of exit site from the iodine-treated group. On the second month of the study, there were two episodes (5.6%), one from the iodine-treated group and one from chlorhexidine-treated group. One episode only for patient from iodine-treated group in the sixth and nine month had infected exit site, compared with 52 who had healthy exit site. The infection rate reached the peak at the seventh month of the study with 4 (7.5%) episodes of exit site infection; 3 (4) from the iodine-treated group and 1 (4) from Chlorhexidine-treated group. It is noticed that these 4 episoides occurred on May during summer session with sever hot weather. The majority of infection was not associated with remarkable degree of drainage, two cases had infection presented with granuloma and swelling over the site. All patient experienced infection did not complain of pain at the exit site. The most common bacterial growth was gram positive bacilli, except one case of gram-positive cocci. Exit site infection was treated based on culture sensitivity including both local and oral antibiotics.

During the study period, there hasn't been any exit site infection associated with tunnel infection or peritonitis. Tunnel ultrasound graph is one of the important examinations used in our center if there is a collection or redness around the external cuff or there is a query of tunnel infection. None of participants from both groups had any redness, collection or tenderness around the tunnel site during exit site infection (Figure 7).

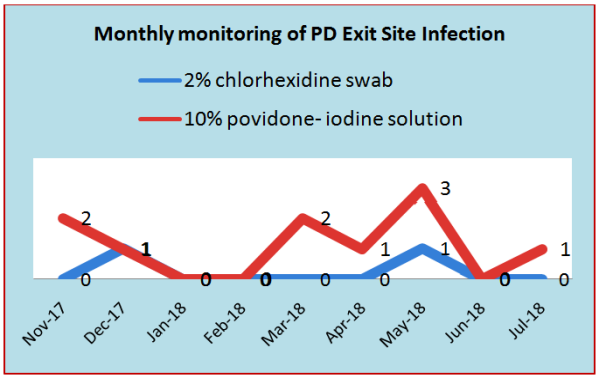

Figure 7: Monitoring of PD catheter exit site infection.

There were 8 (27) patients from treatment group experienced skin reaction after using the 2% chlorhexidine swab stick, 2 (8) patients stopped it after first used and 7 (9) patients hold it after a week. Skin reaction varied from minor to major. Verbal questionnaire done during their monthly visit for treatment group regarding their satisfaction with 2% chlorhexidine swab, 71.4% of total patients were happy to use it and 28.6% were not satisfied with it, all of them (100 %) stated that it is easy and save time, figure 8. The calculated cost for 9months for treatment group was approximately 2200 main Rail ($571.5), whereas the cost was 300 Rail ($779.3) for control group.

PD Catheter integrity for of both groups was assessed during each follow up visit. There was no damaging effect of both reagents on the PD catheter structure and function. The control group was provided with NACL solution (0.9%) to use it along with povidone-iodine. On other hand, patients on Chlorhexidine +alcohol were provided with NACL solution (0.9%) to use it standby if they got skin reaction post reagent application. Moreover, these reagents were used partially for the skin around the catheter exit site not for the catheter itself.

Gram positive bacteria with exit site infection, was the most common cause among both treatments: three patients from the Iodine group got developed had gram positive bacterial and one had gram negative, while from Chlorhexidine group one patient had gram positive and one patient had gram negative bacteria.

Serum albumin and WBC were evaluated monthly for all participants, as given in graph 9. As shown in table 2, serum albumin:

the Mean (SD) for all participants on November 2017 was 26.1 (6.3), 24 (7.5) for treatment group and 28 (4.0) for control group, with non-significant p value. The Mean (SD) of serum albumin was similar on December, February, March and April of 27.8 (4) and almost the same on January, May and July 28.7 (4.2). On June, it reached to 29.2 (3.7), 30.3 (4.3) for treatment group and 28.1 (2.9) for control group and p value was non-significant. Table 3 shows WBC finding during the study period where the Mean (SD) for both groups fluctuated during nine months between 6.5 (2.5) and 8.1 (3.3), for treatment group between 6.8 (2.3) and 8.4 (4) and for control group from 6.2 (2.8) to 7.9 (2.9).

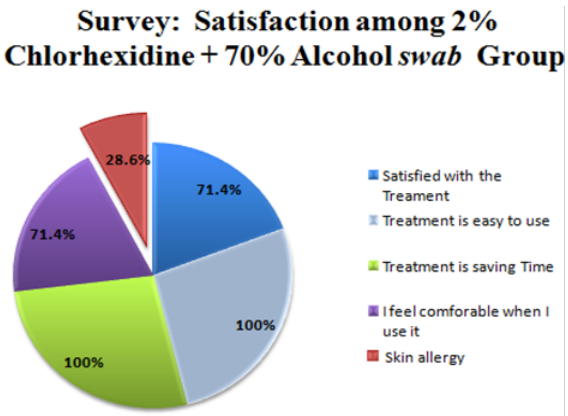

Figure 8: Survey of satisfaction among 2% chlorhexidine and 70% alcohol swab group.

Variables	All	Treatment Group	Control Group
November/ Serum albumin	26.1 (6.3)	24.5 (7.5)	28 (3.96)
December/ Serum albumin	27.8 (4.2)	27.8 (5.2)	27.8 (3.2)
January/ Serum albumin	28.7 (4.5)	27.2 (3.9)	30.2 (4.8)
February/ Serum albumin	27.8 (3.9)	27.3 (3.2)	28.3 (4.3)
March/ Serum albumin	27.4 (3.7)	26.1 (3.2)	28.9 (2.8)
April/ Serum albumin	27.4 (5.3)	27.2 (5.2)	27.7 (5.7)
May/ Serum albumin	28.8 (4.2)	29.4 (5.1)	28.3 (5.3)
June/ Serum albumin	29.2 (3.7)	30.3 (4.3)	28.1 (2.9)
July/ Serum albumin	28.3 (3.8)	28.5 (4.1)	28.1 (3.7)

Table 2: Serum albumin level throughout the months of the study period.

Variables	All	Treatment Group	Control Group
November	6.5 (2.5)	6.8 (2.3)	6.2 (2.8)
December	7.1 (3.7)	6.7 (4.2)	7.6 (3.2)
January	7.2 (2.4)	7.2 (1.8)	7.1 (3.1)
February	6.7 (2.5)	6.8 (2.7)	6.5 (2.4)
March	8.1 (3.3)	8.4 (3.98)	7.9 (2.9)
April	6.6 (3)	7.1 (4.9)	5.95 (1.7)
May	7.7 (3)	8.5 (3.1)	6.97 (1.9)
June	7.1 (2.4)	6.97 (2.6)	7.3 (2.4)
July	6.8 (2.6)	7.1 (3.1)	6.48 (5)

Table 3: White cell count level throughout the months of the study period.

Discussion

This is the first PD RCT study done at the Royal Hospital to evaluate the effectiveness of 2% Chlorhexidine +70% alcohol swab in preventing PD catheter exit site infection versus 10% Povidone Iodine solution over nine months period. It showed that Chlorhexidine-alcohol reduced the risk of PD catheter ESI significantly compared to Povidone Iodine solution. Also, the study found that 2% Chlorhexidine swab +70% alcohol is much cheaper than Povidone Iodine solution and saves time. However, chlorhexidine-alcohol swab can cause skin irritation with varying reaction from mild to severe irritation.

In this study, the mean age for participants was 47 years which is similar to Saudi PD patients in a study done at King Khalid University Hospital [14] and it is very close to Iranian PD patients' age, where their mean age was 46years [15]. Regarding gender, male participation was 38% in our study and it is different than studies in Saudi where male patients were 46% and Iranian male patients were 55%.

Our finding showed that Chlorhexidine- alcohol reduced the risk of PD catheter ESI by double compared to Povidone Iodine solution, were four patients from Iodine group had ESI compared with only two patients from Chlorhexidine group. However, our finding did not approve that, Chlorhexidine alcohol is able to prevent exit site infections totally. There were different opinions regarding the effectiveness of both treatments, some studies supported our finding [8,16,17], others found no difference between them in regard to efficacy [18], while others overbalanced Povidone iodine solution [19]. The study done by Crawford S, Chu G (2014) [8], had a similar finding to our study, where they stated that the result from their project indicated that 2% Chlorhexidine solution may be more effective in managing PD exit site care when compared with 10% Povidone-iodine and even though the results have shown a significant improvement in preventing ESIs when 2% chlorhexidine was used (Figure 9).

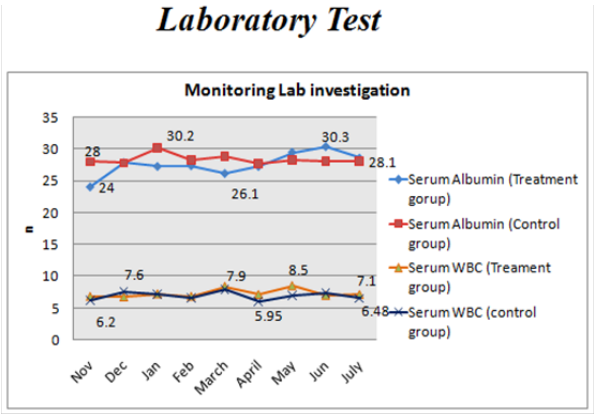

Figure 9: Laboratory Tests during the study period.

Furthermore, in a randomized study done by RO Darouiche [20], assigned adults undergoing clean-contaminated surgery in six hospitals to preoperative skin preparation with either chlorhexidine-alcohol scrub or povidone- iodine scrub and paint, found that, the application of chlorhexidine- alcohol reduced the risk of surgical-site infection by 41% as compared with the most common practice in the United States of using aqueous povidone- iodine.

On other hand, the study of AP Kulkarni [18], which done in India to compare efficacy of chlorhexidine 2% and povidone iodine 10% for skin disinfection prior to placement of epidural and Central Venous Catheters (CVCs) for sixty consecutive adult patients undergoing elective oncosurgery requiring placement of epidural and CVCs were enrolled, reported no difference between them, where no organism was grown after application of either antiseptic solution from any patient.

The Iranian study of N Majidipour [19], where 98 hospitalized infants participants, in each infant, one area on the skin was disinfected by chlorhexidine while the contra lateral site was disinfected by PVP-I. Skin cultures were taken before and after disinfection showed that, both PVP-I and chlorhexidine were effective on reducing skin bacterial flora in infants. However, the effect of PVP-I 10% was significantly more compared with chlorhexidine 2%.

It is very important to consider the cost, when choosing antiseptic. There are not many studies that investigated the cost for both treatments. Our finding reported that 2% Chlorhexidine swab +70% alcohol is much cheaper than Povidone Iodine solution and safe time, the calculated cost for 9 months for treatment group was approximately 220 Omani Rail ($571.5), whereas the cost was 300 Rail ($779.3) for control group. I Lee [21], Meta-analysis and cost data from the Hospital of the University of Pennsylvania carried out, they developed a decision analytic cost-benefit model to compare the economic value, from the hospital perspective, of antisepsis with iodine versus antisepsis with 2 preparations of chlorhexidine (4% chlorhexidine bottle and single-use applicators of a 2% chlorhexidine gluconate [CHG] and 70% isopropyl alcohol [IPA] solution). In the cost-benefit model baseline scenario, switching from iodine to chlorhexidine resulted in a net cost savings of $16-$26 per surgical case and $349,904-$568,594 per year for the Hospital of the University of Pennsylvania.

By contrast, AP Kulkarni [18], found the costs were only marginally different, 40 paisa between chlorhexidine and povidone-iodine, which is very minimal. However, the contact time (application to drying) was much shorter with chlorhexidine in our study. They stated that, the time taken to achieve antisepsis may be important in emergency situations like trauma or emergency caesarean section where epidural or spinal anesthesia or CVC insertion needs to be carried out in a hurry. When time is of essence, chlorhexidine may be preferred to povidone-iodine.

It is well known that both antiseptic solutions can lead to allergic reactions, especially cutaneous hypersensitivity. Our study agreed that chlorhexidine can cause skin irritation with variable reaction differ from mild to severe reactions. We reported nine subjects with skin irritation post application of chlorhexidine-alcohol swab. KM Ho [22], did a randomized-controlled, two-by-two factorial trial, included 2,349 patients from 11 French ICUs in six hospitals. It designed to answer three clinical questions using the same cohort of patients, including (I) is skin scrubbing before intravascular catheter insertion more effective than no skin scrubbing in preventing CR-BSI; (II) is chlorhexidine-alcohol more effective than povidone iodine-alcohol as a skin antiseptic before intravascular catheter insertion in preventing CR-BSI; and (III) does skin scrubbing work better only with a particular type of skin antiseptic (chlorhexidine-alcohol or povidone iodine-alcohol). They reported that, severe skin reactions did occur more frequently in chlorhexidine-alcohol group (3%) than povidone iodine-alcohol group (1%). Despite a reduction in incidence of CR-BSI in the chlorhexidine-alcohol group, there was no significant reduction in length of stay or mortality. They recommended Chlorhexidine-alcohol should be used as a routine skin antiseptic instead of povidone iodine-alcohol before intravascular catheter insertion, with the exceptions in patients who have known or suspected topical or systemic reaction to chlorhexidine.

According to HH Wang [23], who performed Randomized Controlled Trial (RCT) from May 2010 to May 2011 at E-Da hospital in Taiwan with a total number of 119 patients, intervention group received daily cleaning of the exit site and application of 4% aqueous chlorhexidine with a swab and the chlorhexidine was rinsed off by normal saline after 3 min of air-drying and then gauze was applied. The control group received daily cleaning of the exit site and application of normal saline with a swab, followed by gauze. After intervention, there were four patients intolerant of chlorhexidine due to skin itching including one patient who had focal eczema around the exit site.

The present study has some limitations. First, the number of subjects may be small to evaluate and analyze the effect of preventing exit site infections. Secondly, although, all subjects from different treatment groups receive an equal training for exit site caring, but there was no home visit to evaluate their performance at home for both exit site care and hand washing.

In conclusion, the 2% Chlorhexidine swab+ 70% Alcohol is efficient for routine PDC exit site care and reduces the risk of infections. It is a cost-effective and save time. Additional studies with more participants are needed to support these finding.

Compliance with Ethical Standards

Disclosure of potential conflicts of interest

The study was approved by the Scientific Research Committee at the Royal Hospital, Muscat, Oman and certify that the study was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments ethical standards.

Consent for publication

All authors have agreed to the publication and to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Author Contribution Statement: All authors have contributed equally

Informed consent

Each patient was freely given, informed consent to participate in the study.

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Conflict of Interest

Authors declare no conflict of interest but Dr Ayman Karkar works with Baxter company in Dubai, UAE.

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