ABSTRACT

BACKGROUND: The world is facing economical crises and it has particularly affected third world countries. Therefore we must review the controversial health related procedures to save the cost and time without compromising health. The main goal of this study was to assess the need of skin preparation with 70% isopropyl alcohol swab wiping as an antiseptic measure, to prevent infections before intramuscular, subcutaneous and intradermal injections.

DESIGN AND METHOD: Quasi experimental design. Microbiological as well as clinical assessment of pre-injection use of alcohol swabs was studied among the patients who need an injection at King Khalid University Hospital, Riyadh from August 2012 – December 2012.

RESULTS: The mean CFU (Colony Forming Units) per ml over the injection site before alcohol swab wiping were significantly higher (2.47 ± 3.86) than after alcohol swab use (1.31 ± 1.93); p = 0.002. Although, 70% isopropyl alcohol swab reduced skin bacterial counts by 47%, there were no significant difference in clinical signs and adverse local or systemic effect with or without skin preparation by alcohol swab before intramuscular, intradermal or subcutaneous injections.

CONCLUSION: Routine skin preparation with alcohol swab before an injection is quite unnecessary and is of no significant value in safeguarding infection. Omitting skin cleaning with alcohol swab prior to an injection would save time and money.

KEYWORDS: Skin preparation, Alcohol swab, Skin disinfectant.

INTRODUCTION

In medical care therapeutic agents like a drug, vaccine, or contraceptives are introduced into the body using a needle and syringe. According to the World Health Organization (WHO) and Safe Injection Global Network (SIGN), among the most common health care procedures injections are employed by nurses at an estimated rate of 16 billion administrations per year. It is assumed that the skin is contaminated with organisms which might cause pathological changes when introduced into the body through injection needle. On the basis of this assumption medical students, trainee doctors, nurses and patients are taught to have skin prepared before injection by cleansing with some form of antiseptic to prevent infections at the injection site. Since 19th century Alcohol swab (saturated with 70% isopropyl) is used as a highly effective and oldest topical antiseptic for preparing the skin before operation. According to William and his colleagues, alcohol kills most of the vegetative bacteria but has no action on fungal spores. Another study concluded that alcohol does not evaporate rapidly, so that when used some of it may be carried into the body through the skin with the injection needle, giving rise to an unpleasant stinging sensation. The evidence does not support the need for disinfection of the skin before any subcutaneous, intradermal, or an intramuscular injection. One abscess occurs per 12 million injections as described by General practitioners, community practitioners and health visitors association. It is unnecessary to prepare the skin by alcohol swab routinely before intradermal, intramuscular and subcutaneous injection.

For any technology or procedure, knowledge and skill need to be updated to make sure that behavior is consistent with current best practices. Now a days, according to the policy guidelines in King Khalid University Hospital Riyadh, Saudi Arabia and many other health care centers of the world, use of alcohol swab for the preparation of skin before injection is mandatory.

In view of the global recession the third world countries should review the controversial health related procedures which might save the cost and time without compromising health. One should not forget the lesson learned from 10,000 blind neonates due 100% oxygen given to preterm babies, a policy that was revised later. Medical procedures should be evidence based and not suggestion or good intention based to yield the best comes clinical as well as economical. It is therefore we conducted this study to have evidence needed to address this important issue regarding the preparation of skin with 70% isopropyl alcohol swab before intradermal, subcutaneous and intramuscular injections. The findings of the study are expected to help in deciding whether to prepare or not to pre-
pare the skin by wiping it with 70% isopropyl alcohol swab before an injection.

**METHODOLOGY**

**Design:** Quasi Experimental Design:
A quasi-experimental design is one that looks a bit like an experimental design but lacks the key ingredient --- random assignment.

**Setting:** The study was conducted at King Khalid University Hospital which is attached with college of Medicine, King Saud University, Riyadh.

**Assessment:** We assessed the need for use of 70% alcohol swab for the skin preparation before injection by two different ways, clinical assessment and pathological assessment.

**Clinical assessment (Physical examination):**
For this aspect of assessment, from August 2012 – December 2012, we enrolled 407 volunteer patients who agreed to participate in the study. The Subjects were randomly taken from different clinics of the hospital, the nature, purpose and possible risks of the study was explained before their verbal consent to participate.

Clinical effects of routine skin preparation with 70% isopropyl alcohol and the effects of no preparation of skin before injection were studied. Patients were allocated to the two following groups;
1. Patients who received intramuscular (IM), subcutaneous (SC) or intradermal (ID) injection after skin preparation with a 70% isopropyl alcohol swab (221 subjects)
2. Patients who received injection without skin preparation (186 subjects).

Overall drop-out rate due to lost to follow was 24% (59 participants in 1st and 38 in 2nd group). Remaining 310 participants (162 in 1st and 148 in 2nd group) were analyzed statistically.

The area of injection was assessed in both groups after 2-3 days by an independent observer (family physician), who was blind to swab status. Erythma, pain, swelling, fever and abscess formation were assessed in both groups for analysis.

Patients positive for any of the above mentioned signs were asked to inspect the injection site carefully and were asked to note the redness, tenderness or any other abnormal sign over the injection sites. The clinical signs positive patients were further observed over a period of 3 weeks on weekly basis for any local or systemic effect by an independent observer (family physician).

**Pathological assessment:**
During August 2012 – December 2012, fifty one volunteer patients from different clinics in the hospital were enrolled for this aspect of the assessment. In all subjects the effect of routine skin preparation with alcohol swab and the effect of no skin preparation before injection were studied by assessing the skin bacterial colony forming units (CFU) per ml.

It was assured that none of the participant had skin disease or co morbidity (immunosuppressed or any heart valve disease) at the time of inclusion in the study. We took swab for culture from the site of injection (as per instructions by a consultant microbiologist of the hospital) before and after the alcohol swab wiping from all the enrolled participants (n=51) i.e. a total of 102 skin swab cultures, to assess the effect of skin preparation by 70% isopropyl alcohol swab, pathologically.

- 1st culture was taken by a dry sterilized cotton swab from the injection site (before wiping with 70% isopropyl alcohol swab). The site was then scrubbed with moderate pressure with alcohol swab for 30 seconds, allowed to dry for another 30 seconds then injection was given.
- 2nd swab for culture was taken after giving the injection (prior scrubbed with alcohol swab).

We counted the CFU of all the culture positive patients and analyzed statistically. The culture positive patients were observed over a period of 3 weeks on weekly basis for any local or systemic effect by an independent observer (family physician).

**Colony Forming Units (CFU / ml):**
The viable bacterial or fungal numbers are measured by colony-forming unit (CFU) in microbiology. CFU measures viable cells unlike in direct microscopic counts where all cells, dead and living, are counted. Basically, it is used as a measure of the number of microorganisms present in or on surface of a sample.

**Ethics:**
Approval of the hospital ethic committee was obtained for the study. All enrolled participants gave informed consent.

**Statistical Analysis:**
We entered the data into spread sheet & processed on SPSS-16 package. We used descriptive analysis for summarizing basic demographic data, bacterial colonies forming units (CFU / ml) were counted from all the positive cultures and analyzed statistically. Data are presented as the Mean ± SD unless otherwise noted. Differences between two groups of data were analyzed by Student’s t-test.

**RESULTS**
We enrolled patients of both sexes and all age groups.
for clinical as well as microbiological assessment (Tab I). None of the patient had any immunological or heart valve disease at the time of enrollment.

**Clinical outcome:** A total of 407 injections were given by intramuscular, intradermal and subcutaneous routes, using different drugs (excluding anti microbial drugs) and vaccines to assess any infection clinically. Drop out rate in clinical assessment group was very high (24%). ‘Lost to follow’ was the only cause of drop outs. Most of the patients (68%) having erythema or swelling were in the group of intradermal injection (PPD) for tuberculosis screening. There was no statistical difference related to observed clinical signs among both groups (Table II). All the patients having positive clinical signs were followed on weekly basis for 3 weeks by direct or telephonic consultation. At the end of 3 weeks, all the physical signs had disappeared and there were no local or systemic evidence of infection.

**Pathological outcome:** Majority of patients (70%) culture positive were under 1 year of age.

In patients before alcohol swabbing, total sum of 126 CFUs (ranging from 2-12 CFU per patients) in 18 patients out of 51 (35%) were positive for growth and 33 patients had no growth. The organism mainly found was staphylococcus epidermidis.

After alcohol swabbing, the sum of 67 CFUs (ranging from 2-6 CFU per patients) in 20 patients out of 51 (39%) were positive for growth and 31 patients had no growth.

The number of CFU was decreased significantly by 47% after alcohol swabbing. The mean CFU per ml for patients without alcohol swabbing was significantly high (2.47±3.86), compared to CFU per ml after wiping with alcohol swab (1.31±1.93), as shown in table 3 (p = 0.002).

All the patients having positive culture were followed on weekly basis for 3 weeks by direct consultation or by their given contact numbers. At the end of three weeks, none of the patient in both groups had any local or systemic adverse effect.

**Time and Cost:** In the same setting, we also calculated the time spent for skin preparation with alcohol swab and the cost of alcohol used for vaccination in children (table IV). Precious time (3.4 days per month) of nursing staff was spent for preparing the skin for vaccinating children and more than US$ 26 per month was spent to buy the alcohol swabs for wiping the skin before injecting a vaccine.

| TABLE I: BASIC CHARACTERISTICS OF STUDY PARTICIPANTS |
|-----------------|-----------------|-----------------|-----------------|
|                  | Intramuscular    | Subcutaneous    | Intradermal     |
|                  | (n=196)          | (n=68)          | (n=46)          |
| Participants having Injection without skin preparation (n=148) |                  |                  |                  |
| Mean age in years (range) | 26 years (1 mon-66 years) | 19 years (6mon – 32 years) | 23 years (1 week – 36 years) |
| Male : Female | 1 : 1.2 | 1 : 1.1 | 1 : 1.13 |
| Saudi : Expatriates | 1 : 0.34 | 1 : 0.22 | 1 : 0.86 |
| Co morbidity (i.e. immunosuppressed, heart valve lesion) | Nil | Nil | Nil |
| Participants having Injection after skin preparation (n=162) |                  |                  |                  |
| Mean age (range) | 24.5 years (1 mon–58 years) | 23 years (5mon – 38 years) | 19 years (1 week-44 years) |
| Male : Female | 1 : 1.1 | 1 : 0.96 | 1 : 1.2 |
| Saudi : Expatriates | 1 : 0.18 | 1 : 0.16 | 1 : 0.65 |
| Co morbidity (i.e. immunosuppressed, heart valve lesion) | Nil | Nil | Nil |
| Participants for Pathological assessment (n=51) |                  |                  |                  |
| Mean age (range) | 12.5 years (7 mon – 56 years) | | |
| Male : Female | | 1 : 0.7 | |
| Saudi : Expatriates | | 1 : 0.31 | |
| Co morbidity (i.e. immunosuppressed, heart valve lesion) | | Nil | |
TABLE II: CLINICAL OUTCOME OF PATIENTS (ON DAY 2 OR 3) WITH AND WITHOUT SKIN PREPARATION BEFORE INTRAMUSCULAR, INTRADERMAL AND SUBCUTANEOUS INJECTION

<table>
<thead>
<tr>
<th></th>
<th>Injection without skin preparation</th>
<th>Injection with skin preparation</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n=148)</td>
<td>(n=162)</td>
<td></td>
</tr>
<tr>
<td>Erythema</td>
<td>26 (17.57)</td>
<td>31 (19.14)</td>
<td>&gt; 0.05</td>
</tr>
<tr>
<td>Pain</td>
<td>17 (11.49)</td>
<td>24 (14.81)</td>
<td>&gt; 0.05</td>
</tr>
<tr>
<td>Swelling</td>
<td>19 (12.84)</td>
<td>26 (16.05)</td>
<td>&gt; 0.05</td>
</tr>
<tr>
<td>Cellulitis</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Abscess formation</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Fever or other signs of systemic infection</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

DISCUSSION

Our study shows that skin preparation with alcohol swab destroys 47% of skin bacteria at the injection site. No skin preparation with alcohol swab before injection did not result in clinically demonstrable signs of infection. As we did not compare alcohol wipe with placebo wipe, it is not possible to comment on mechanical removal of skin bacteria.

Theoretically, skin is the largest organ of the body it serve to protect against heat, light, injury and infection. It also regulates the body temperature, storage of water and fat. It is a sensory organ, preventing water loss and bacterial entry. A large number of organisms live harmlessly on human skin as commensals on its surface. Elek has shown that a minimum dose of $7.5 \times 10^6$ staph aureus are needed for pus formation after an intradermal injection.¹⁰

In our study the mainly found organism was staphylococcus epidermidis and the number of CFU on an uncleaned skin site were ranging from 2-12 as compared to 2-6 for well cleaned skin. When we take account of the tiny surface area needed for an injection, it is apparent that the number of bacteria injected in an uncleaned site is quite lower than that which is required for pus formation.

Various controlled studies comparing the risk of infections related to injections revealed no significant signs of infections among both group of patients who had or had not any skin preparation.

Fleming observed more than 13,000 insulin injections with and without skin preparation with alcohol over the period of 20-weeks and did not find any signs of infection at injection site in both groups.⁴ Border observed 254 patients on insulin and found no infection at 2828 injection sites.⁵ Similarly in six years, Dann observed more than 5000 injections given by all routes without using any form of skin preparation and found no single

TABLE III: PATHOLOGICAL OUTCOME/CULTURE RESULTS

<table>
<thead>
<tr>
<th>Skin Swab culture results</th>
<th>Pre alcohol CFU (Mean ± SD)</th>
<th>Post alcohol CFU (Mean ± SD)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colonies forming units per ml (CFU/ml)</td>
<td>126 colonies (2.47±3.86)</td>
<td>67 colonies (1.31±1.93)</td>
<td>P 0.002 (47 % decrease in colonies after swabbing)</td>
</tr>
<tr>
<td>Number of pts having No growth</td>
<td>33 (65 %)</td>
<td>31 (61 %)</td>
<td></td>
</tr>
<tr>
<td>Total pts</td>
<td>51</td>
<td>51</td>
<td></td>
</tr>
</tbody>
</table>

TABLE IV: MONTHLY STATISTICS OF VACCINATION, CALCULATING THE EXTRA TIME FOR SWABBING AND THE COST FOR ALCOHOL AT KING KHALID UNIVERSITY HOSPITAL RIYADH, SAUDI ARABIA

<table>
<thead>
<tr>
<th>Month</th>
<th>Total vaccination</th>
<th>Time taken for skin preparation (30 seconds for swabbing &amp; 30 seconds to dry = 1 min / patient)</th>
<th>Total swabs (100 swabs/box)</th>
<th>Cost (1.6 US$/box)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug 2012</td>
<td>1434</td>
<td>23.90 hrs = 2.99 days*</td>
<td>15 boxes</td>
<td>US$ 24</td>
</tr>
<tr>
<td>Sep 2012</td>
<td>1205</td>
<td>20.08 hrs = 2.51 days*</td>
<td>12 boxes</td>
<td>US$ 19.2</td>
</tr>
<tr>
<td>Oct 2012</td>
<td>1709</td>
<td>28.48 hrs = 3.56 days*</td>
<td>17 boxes</td>
<td>US$ 27.2</td>
</tr>
<tr>
<td>Nov 2012</td>
<td>1745</td>
<td>29.08 hrs = 3.64 days*</td>
<td>17.5 boxes</td>
<td>US$ 28</td>
</tr>
<tr>
<td>Dec 2012</td>
<td>2061</td>
<td>34.35 hrs = 4.29 days*</td>
<td>20.5 boxes</td>
<td>US$ 32.8</td>
</tr>
<tr>
<td>Average per month</td>
<td>1631</td>
<td>3.4 days</td>
<td>16.4 boxes</td>
<td>US$ 26.24</td>
</tr>
</tbody>
</table>

* = days are calculated by the nursing working time i.e. 8 hours per day.
case of infection. McCarthy studied infections in 50 patients who were on insulin. He compared 600 injections with skin preparation by alcohol wipe, 600 injections with cotton soaked in tap water and 600 injections without any skin preparation, over the different three quarters of abdomen. He concluded that none of the patients experienced injection site complication from any of the three methods. Microbiological studies also do not suggest that wiping the skin with any antiseptic before intradermal, subcutaneous and intramuscular injections reduces the risk of infection. Koivisto and Felig measured skin bacterial flora after 5 seconds of skin wiping with 70% isopropyl alcohol swab and found 82-91% reduction in bacterial count. In the same study, comparison of 1700 insulin injections which preceded by skin preparation with alcohol swab and 1700 without skin preparation with alcohol swab revealed no local or systemic infection during 3-5 months observation. In another study, seventeen patients reused 111 disposable insulin syringes for a total of 2363 times but did not experience any injection site infection. Infections, however, are just as likely to arise from using infected syringes and needles, or even infected injection solutions, as from piercing contaminated skin. The risk of bacterial infections among injecting drug users could be low with skin cleansing. However, the numbers introduced and virulence of skin bacteria are lower than the minimal infectious dose for pus formation. Therefore, preparing the skin of a person for good hygienic skin is unnecessary. According to WHO and its Safe Injection Global Network (SIGN), "Swabbing of the clean skin prior to giving an injection is unnecessary". WHO further recommends that 'wash the skin that is visibly soiled or dirty. If swabbing with an antiseptic is selected for use, use a clean, single-use swab and maintain product-specific recommended contact time.' This study indicates that skin preparation with alcohol is not always required. This finding is similar to several other studies mentioned above. Omitting skin preparation when it is not required, saves time, money and helps to avoid some of the pain associated with the injection of non evaporated alcohol into the skin.

CONCLUSION

The concept underlying the preparation of skin before injections by wiping it with an alcohol swab as an antiseptic measure to prevent infection was examined critically in this study and the commonly used technique was found to be inadequate as a safeguard against infection. The study also demonstrated that though the skin swabbing before injection significantly decreased the number of bacteria (skin flora), but there was no significant difference among clinical signs and adverse local or systemic effects with or without skin preparation with alcohol swab before intramuscular, intradermal and subcutaneous injections.

SUGGESTIONS

The findings of this study may be used to develop and implement a policy by local policy makers to avoid routine skin wiping with an alcohol swab before administering of injections. It will also save time and money by not performing this unnecessary practice.

LIMITATION OF STUDY

The study checked entry of the organisms through skin which was penetrated same in all three ways of putting injections i.e intramuscular, subcutaneous or intravenous which were not tested separately. A further study will be needed for testing this.

ACKNOWLEDGEMENT

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