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Evaluation of C-Arm Drapes Contamination in Orthopedics Theatre

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ABSTRACT

Background The difficulty encountered during the imaging manoeuvring is to keep both ends of the C-arm well covered with sterile drapes without disturbing the integrity of the surgical field and de-sterilizing the surgeon or the instruments. The C- arm drape contamination may carry additional source of surgical site contamination and infection.
Patients and Methods: Forty-six orthopedic operations were carried out at Orthopedic referral major hospital with the use of C-arm, swabs were collected from C-arm draping preoperatively and postoperatively to evaluate C-arm draping contamination. This was correlated with operations time, traffic in the operating room, door opening frequency during surgery and C-arm Lateral position frequency. The level of contamination was determined according to type of species isolated. **Result:** Both C- arm tube and intensifier were sterile before almost all operations, but C- arm tube became contaminated postoperatively in 87 % of operations performed. The most isolated species were Coagulase Negative Staphylococcus (CONS) . The mean time of the operation, lateral frequency of C- arm, person number within operation room, and door opening frequency were higher in one species and two species groups than no growth group (>100 minutes, p=0.002), (>7 times, p <0.001), (> 5 persons/hr, p <0.001), and (>10 door openings, p <0.001) respectively.
Conclusion: From the present study, we concluded that C-arm drapes carries an inherent contamination risk that can spread to an operational area; in particular, with long duration of the operation, frequently lateral positioning of c-arm, presence of a greater number of personnel in the operating room and high door opening frequency during the surgery.
Keywords: C-arm, Orthopedic Surgeries, Draping, Surgery time, Lateral frequency.

INTRODUCTION

Despite use of the most current techniques to minimize contamination during surgery (e.g., laminar flow operative rooms, ultraviolet lighting, sophisticated implant sterilization, peri-operative antibiotics, and modern surgical preparation and draping procedures), postoperative infection still occur and it is a morbid complication, frequently leading to multiple operations, long-term use of antibiotics with their associated side effects, pain, and potential prolonged disability [(1-3).]

Since the introduction of intra-operative fluoroscopy in the 1950s, no standard draping method or drape has been devised to protect the integrity of the sterile field while the lower portion of the C-arm (x-ray tube) repeatedly rotates from the unsterile zone into the sterile field [(4)].Operative fracture care frequently involves the use of intraoperative imaging, with fluoroscopy being most common in imaging to a controlled reduction of long bone fractures and accurate placement of internal or external fixation devices, requires numerous changes and re-adjustments of the C-arm position are necessary to obtain the desired views. The difficulty encountered during the manoeuvring is to keep both ends of the C-arm well covered with sterile drapes without disturbing the integrity of the surgical field and de-sterilising the surgeon or the instruments [(5-7)].

Aim of this study: was to evaluate the level of C-arm draping contamination in correlation with operation time, frequency of lateral positioning of C- arm, traffic in the operating room and door opening frequency.

MATERIAL AND METHODS

This study was carried out at Orthopedic referral major hospital. Facility Review Board Approval was obtained prior to samples collection. Among 46 orthopedic operations performed on 35 patients -multiple procedures for one patient- with the use of C-arm. Swabs were collected from C-arm draping preoperatively and postoperatively to evaluate C-arm draping contamination in relation to operation time, traffic of operating room, door opening frequency during surgery and C-arm Lateral position frequency.

Study Duration: Study was conducted within time period of September 2019 to March 2020.

Sampling Exclusion Criteria: Exclusion criteria were non-use of a C-arm, using C-arm without skin incision or draping, Secondary draping (re-draping during surgery due to surgical field breach).
C-arm model: General Electric Model (OEC 9800) Plus mobile fluoroscopic imaging systems were used (General Electric Company **TM**, Fairfield, CT).
Surgical Drapes type: Non-woven disposable drapes.

Sample Collection: Two swabs locations (tube and intensifier) were chosen because they were most likely to get in touch with the surgeon and have a higher degree of contamination reported. The centers of C-arm tube and intensifier drapes were determined and area of 3 cm X 3 cm was swabbed with cotton swab. Swabs were transported to a local laboratory immediately (Medical Research Institute). The swabs were cultured on blood, MacConkey's and Sabaraud's agar plates. The plates

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were incubated for 24-48 hrs and evaluated for microbial growth.

Samples identification: Gram stain was carried followed by chemical tests for species identification [8].

Level of contamination: Level of contamination was determined according to type of bacterial species isolated (No growth, one species, two species).

Time recording: Time was rounded to the nearest minute, under direct observation, digital hour used to record each operation time in minutes from skin incision till skin closure. Time was documented in minutes.

Recording of C- arm Lateral Frequency: Counting of the frequency of C-arm lateral positioning were done recording by each transfer between horizontal and vertical position of C-arm tube and intensifier.

Traffic of operating room: The total number of time employees spent in the room during a process (total person-hours/hr of the study time per operation) reported for each operation was tracked by the activity room traffic. **Equation:** calculate time in minutes for each person in operation room then total minutes divided by total operation duration in minutes to give persons number per hour.

Door opening frequency: The Door opening recorded for each operation via enumeration of flap door opening that effect on air movement within operation room. Any person who entered or went out of the operational suite was calculated as one door opening.

Data Collection: Data were collected and assumed on excel sheet in two forms for patient data, operation circumstances and culture results.

Statistical analysis: Data were analyzed using SPSS ver.20 Chicago, IL, USA. Qualitative variables were described using frequency and percent. Quantitative variables normality was tested using Kolmogorov-Smirnov test. Quantitative variables were described using mean, standard deviation if they are normally distributed or by median, minimum and maximum if not normally distributed. Post hoc to analyze the results of triple group data.

Ethics approval and Consent to participate: The study was approved by the Medical Ethics Committee, Medical Research Institute. Patients are not included in this study to provided written consent.

RESULTS

Majority of cases in which C- arm were used were in age group less than 20 years representing 34.3 % of cases while only few cases above 50 years (8.6%). As well, males were dominant female presenting 69.6%. The Most frequently diagnosis were fractures related to Traffic Road Accident presenting 68.6 %. As well majority of surgery type with C arm using were Open Reduction Internal Fixation (ORIF) presenting 80% as shown in Table (1).

Table (1): Distribution of the studied cases according to the demographic data:

Characteristics	n	%
Age		
▪ Less than 20	12	34.3
▪ From 20 to <30	4	11.4
▪ From 30 to <40	11	31.4
▪ From 40 to <50	5	14.3
▪ ≥ 50	3	8.6
Gender		
▪ Male	24	69.6
▪ Female	11	31.4
Diagnosis		
▪ Genu Varum	4	11.4
▪ Spastic diplegic	4	11.4
▪ Stress Fracture	3	8.6
▪ Road Traffic Accident RTA (Fractures)	24	68.6
Surgery Type		
▪ Ilizarove	4	11.4
▪ Implant removal	3	8.6
▪ Open Reduction Internal Fixation (ORIF)	28	80
Total	**35**	**100%**

Both C- arm tube and intensifier were sterile before almost all operations, but C- arm tube became contaminated postoperatively in 87% of operations performed, 67.4 % of them is due to CONS, 17.4 % due to mixed CONS and Gram negative bacilli species and 2.2% due to Gram negative bacilli species. On the other hand C- arm intensifier became contaminated in 82.6% of operations performed, 80.4% of them is due to CONS and 2.2% due to mixed CONS and Gram negative bacilli. The results show no fungal species were isolated as well the most isolated species are (CONS). (Table 2).

Table (2): Percentage of different bacterial species in both tube and intensifier pre and post operative:

Micro-organisms	C- arm tube (N=46)		C- arm intensifier (N=46)	
	Pre-operative n (%)	**Post-operative** n (%)	**Pre-operative** n (%)	**Post-operative** n (%)
No growth	45 (97.8)	6 (13)	46 (100)	8 (17.4)
Gram positive bacillus	1 (2.2)	-	-	-
Coagulase Negative Staphylococcus (CONS)	-	31 (67.4)	-	38 (82.6)
Gram negative bacilli	-	1 (2.2)	-	-
Mixed CONS and Gram-negative bacilli	-	8 (17.4)	-	1 (2.2)
Fungus	-	-	-	-

Table (3) shows that there is a highly significant difference in contamination percentage in the two parts of C-arm fluoroscopy (intensifier and tube) before and after operation (p<0.001). In C-arm tube, 13% of drapes were sterile pre and post operative compared to 84.8% of drapes were sterile preoperatively and become contaminated postoperatively. On other hand C-arm intensifier, 17.4% of drapes were sterile pre and post operative compared to 82.6% of drapes were sterile preoperatively and become contaminated postoperatively.

Table (3): Comparison of contamination percentage in C- arm pre and post operative:

C- arm tube				
Pre-operative contamination	**Post-operative contamination n (%)**			**Test of significance (McNemar test)**
	No growth	***Bacterial growth***	***Total***	
No growth	6 (13)	39 (84.8)	45 (97.8)	$\chi^2_{mcnemar}$ = 26.04 P < 0.001**
Bacterial growth	0 (0)	1 (2.2)	1 (2.2)	
Total	6 (13)	41 (87)	46 (100)	
C- arm intensifier				
Pre-operative contamination	**Post-operative contamination n (%)**			**Test of significance (McNemar test)**
	No growth	***Bacterial growth***	***Total***	
No growth	8 (17.4)	38 (82.6)	46 (100)	$\chi^2_{mcnemar}$ = 25.04 P < 0.001**
Bacterial growth	0 (0)	0 (0)	0 (0)	
Total	8 (17.4)	38 (82.6)	46 (100)	

McNemar: McNemar test (**): p is highly significant

According to operation circumstances (Operation duration, Lateral C-arm positioning, Door opening frequency and Traffic in operating room) and contamination level in C- arm tube as shown in table (4 and 5) : All of them were significantly different among different contamination levels (p=0.002, <0.001, <0.001, 0.001)

Table (4): Comparison of operation circumstances in different contamination levels of C- arm tube:

Operation circumstances	**Contamination levels**			**Test of significance**
	No Growth	**One species**	**Two Species**	
Mean time of operation in minutes	100.83 ± 18.55 (a)	150 ± 39.47 (b)	179.44 ± 42.46 (b)	F= 7.794 P=0.002**
Mean lateral Frequency of C- arm	5.17 ± 2.137 (a)	14.55 ± 5.246 (b)	17 ± 4.87 (b)	F= 11.934 P<0.001**
Mean door Opening Frequency	10.33 ± 2.34 (a)	30.7 ± 11.61 (b)	34.78 ± 13.22 (b)	F= 9.755 P<0.001**
Median number of persons within OR	6 (5-7) (a)	9 (7-14) (b)	10 (7-12) (b)	$Kw_{(2)}$ = 14 P =0.001**

F: one way ANOVA test , Kw: kruskal Wallis test (*): p value is significant (**): p is highly significant

After pairwise comparison (post hoc test):

Mean time of the operation was higher in one species and two species (b) groups (150 ± 39.47, 179.44 ± 42.46 mins) than no growth (a) group (100 ± 18.55) (p = 0.026, 0.001 respectively), but no statistical significant difference was found between groups of one and two species (p =0.184).

Mean lateral frequency of C- arm was higher in one species and two species (b) groups than no growth (a) group (p = 0.001, <0.001 respectively), but not statistically significant difference was found between groups of one and two pathogens (p =0.637).

Mean door opening frequency was higher in one species and two species (b) groups than no growth (a) group (p = 0.001, 0.001), but no statistically significant difference was found between groups of one and two pathogens (p =1). Also, median person number within operation room was higher in one species and two species (b) groups than no growth (a) group (p = 0.001, 0.003 respectively), but no statistically significant difference was found between groups of one and two species (p =1).

Table (5): Comparison of operation circumstances in different contamination levels of C- arm intensifier

Operation circumstances	Contamination levels			Test of significance
	No Growth	One species	Two Species	
Median time of operation in minutes	100 (75-100)	150 (90-240)	-	u = 30.5 P=0.002 **
Mean lateral Frequency of C-arm	5.25 ± 2.6	16.04± 4.47	-	$T_{(24)}$= -4.227 P<0.001**
Mean door Opening Frequency	10.875 ± 2.36	33.401 ± 11.17	-	$T_{(22.9)}$= -7.364 P<0.001**
Mean number of persons within OR	6.25 ± 0.71	9.48 ± 1.65	-	$T_{(23.3)}$= -6.638 P<0.001**

t: independent t test u: Mann Whitney test (*): p value is significant (**): p is highly significant

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DISCUSSION

Among 46 orthopedic operations were studied, C-arm drapes become contaminated at the end of 38 orthopedic operations in C-arm Intensifier drapes and 40 orthopedic operations in C-arm Tube drapes. The contamination level was correlated with increase surgery time, lateral frequency, door opening and traffic in operating room. In the current study, Mean time of the operation was higher in one and two pathogen groups contamination of C-arm tube than no pathogen group (p = 0.026, 0.001 respectively), but no statistical significant difference was found between groups of one and two pathogens (p =0.184). As well, Median time of the operation was higher in c-arm intensifier contamination than non-contaminated C-arm intensifier, (p = 0.002).

Similar results by **Peters** *et al*, the median time from the start of the operation to contamination of the C-arm cover was 20 min (95% confidence interval [CI] 2, 38 min). There was a 17% contamination rate on draping, 50% at 20 min, 57% at 40 min, and 80% at 80 min. In five cases (16.7%), the C-arm did not become contaminated during surgery [9, 10]. Other similar results in a prospective study by **Biswas** *et al*, evaluated the sterility of 25 C-arm drapes placed with aseptic technique after their use during spine surgery. The average time for C-arm drape contamination was 101 ± 66 minutes [1].

Based on these findings, contamination of C-arm drapes occur often and sometimes early during orthopedic surgeries and contamination level increase with operation's time increasing. We found in the current study that Mean lateral frequency of C- arm was higher in one and two species groups of contamination of C- arm tube than no C- arm tube contamination groups, (p = 0.001, <0.001 respectively), but not statistically significant difference was found between groups of one and two species (p =0.637). Also, mean lateral frequency of C- arm was higher in pathogens contamination of C-arm intensifier groups than no contamination group, (p <0.001). In contrast with this study results, **Biswas** *et al*, found that the average number of times that the C-arm was moved into the lateral position was 1.8 ± 1.2 times. The end of the beam receiver and the front portion of the upper C-arm were found to be contaminated in 56% (*P*=0.0000095) and 28% (*P*=0.01), respectively, of cases performed at our institution [1].

Similar to our results, **Peters** *et al*, found with the mean rotations to the lateral position 1.63 – 1.54 times amount of contamination occurs on the C-arm drape by the end of a spine case [9].

According to these data, maintaining the sterility of the C- arm is still a challenge to be tackled by the surgical instruments, our findings suggest that C-arm contamination is an issue that may involve all areas of the lining, while the use of different x-rays is more frequently influenced by some areas of the image intensifier than by others. In this study, median person number within operation room was higher in one and two pathogen of C-arm tube contamination groups than no contamination group (p = 0.001, 0.003 respectively), but not statistically significant difference was found between groups of one and two pathogens (p =1). And mean person number within operation room was higher in pathogen of c-arm Intensifier contamination groups than no contamination group (P<0.001).

Similar to our results in study conducted by **Biswas** *et al*, found that total no. Of personnel within OR 3.6 ± 0.6 may correlate to C-arm parts contamination [1].

Also, **Andersson AE** *et al*, conducted an observational study investigated the air quality during 30 orthopaedic trauma procedures and showed a positive correlation between microbial airborne load and the number of people present in the OR[11]. In accordance with our results, A systematic review performed by **Birgand G** *et al*, on 14 studies to assess the impact of surgical-staff behaviours on the risk of SSI identified a correlation between the number of people in the OR and SSI rate or airborne contaminants [12].

In the current study, mean door opening frequency was higher in one and two pathogen of c-arm tube contamination groups than no contamination group (p = 0.001, 0.001), but no statistical significant difference was found between groups of one and two pathogens (p =1). And for intensifier, mean door opening frequency was higher in pathogen of C-arm intensifier contamination groups than no contamination group (p < 0.001). Similar to these results, **Peters** *et al*, found that the mean door openings 68 ± 22 times was correlated positively with contamination of c-arm drapes (r= 0.64; p = 0.003) [9]. In view of the above studies, increase door opening frequency interrupte air within OR and air

entering from outside and showed positive correlation with air contamination. They reported that contamination of the C-arm drape is frequently airborne, meaning that the arm does not become contaminated through direct contact with a non-sterile object. Subsequent contact with the C-arm cover can then lead to cross-contamination of the surgical field [1, 12].

The highest rates of C-arm drapes contamination during orthopedic operations were obvious in the lower portion of the C-arm (C-arm tube). This Contamination is most likely caused by the rotation of unpacked sections of the C-arm to collect lateral images. In such a case, the lower portion of C-arms is no longer considered sterile, and we agree that the risk of intraoperative contamination and potentially postoperative infection can also be reduced if encounters with these areas are prevented. There are few studies interested in C-arm drapes contamintion. So, there are no adeqaute studies to support or negates the results in the current study. As well, many companies carried out studies to start marketing of their products, therefore these studies were not included here to exclude bias that may be found in their results. Limitation of the current study are; air contamination in operation room correlation with C- arm draping contamination were not studied, as well, micro-organisms were isolated cannot be considered pathogenic species, Lack of follow up for surgical site infection in 35 patients make it difficult to corrolate C- arm drapes contamination with SSIs and correlation of Operation room circumstances (Operation duration, Lateral C-arm positioning, Door opening frequency and personal number during operation) with operation room air contamination were not studied.

CONCLUSION

From the present study, we conclude that C-arm drapes contamination level carries an inherent contamination risk that can spread to an operational area; in particular, with long duration of the operation, frequently lateral positioning of c-arm, presence of a greater number of personnel in the operating room and high door opening frequency during the surgery.

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RECOMMENDATIONS

1. Technicians must be trained to overcome C-arm contamination by place the C- arm over the limb 's top instead of underneath.
2. A study of broad sample and several confounding variables are recommended for the purpose of certainly confirming the C- arm drapes contamination relation to operation room air contamination.
3. Post-operative patient follow up is needed to determine correlation between C-arm drapes contamination and Surgical Site Infections.

ABBREVIATIONS

SSI:	Surgical Site Infection
OR:	Operation Room
CONS:	Coagulase Negative *Staphylococcus*
CFUs :	Colony Forming Units
SDA :	Sabaraud's Dextrose Agar
sp. :	Species
X^2:	Pearson Chi square test

DECLARATIONS

- **Consent for publication:** Not applicable
- **Availability of data and materials:** The datasets generated and/or analysed during the current study are not publicly available due confidentiality reasons and institutional policies.
- **Competing interest:** None is declared.
- **Funding:** This research work was not funded.

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