The effect of iodine impregnated incise drapes on the incidence of surgical site infections following abdominal surgeries in children in Nigeria

Ugwunne C A, Osuigwe A N, Ekwunife OH, Ugwu J O, Modekwe V I,
Paediatric Surgery Unit, Department of Surgery, Nnamdi Azikiwe University Teaching Hospital, P.M.B 5025 Nnewi, Anambra State, Nigeria.

Abstract

Background: Surgical Site Infections (SSIs) impose a substantial burden of morbidity and mortality which in turn imposes a heavy demand on health care resources. Considering this burden, SSI initiatives have shifted from treatment to prevention as majority of SSIs are preventable. Antibiotic impregnated drape is one of the strategies to reduce SSI and has been shown in adults to reduce SSI. This has not been tested in children.

Objective: To determine the effect of iodine impregnated incise drapes on the incidence of SSI following abdominal surgeries in children.

Method: This study was a prospective randomised study in which 120 children undergoing clean and clean contaminated abdominal surgeries were randomised into two groups: A and B, of 60 each. Iodine impregnated incise drapes was used in Group A while it was not used in Group B. Postoperatively, the patients were followed up for 30 days and SSI identified and graded with the modified Southampton wound grading system. Statistical analysis was done using IBM SPSS Statistics V21.0.

Result: The SSI rate for clean abdominal surgeries with the use of iodine impregnated incise drapes was 10% compared to 13.3% without the use of iodine impregnated incise drapes (P = 0.668). For clean contaminated abdominal surgeries, the SSI rates were 13.3% and 26.6% with and without the use of iodine impregnated incise drapes respectively (P = 0.155).

Conclusion: Iodine impregnated incise drapes did not have any significant effect on SSI rate following clean and clean contaminated abdominal surgeries in children.

Key words: SSI, Ioban, Abdominal Surgeries

Introduction

Surgical site infections (SSIs) are defined as infections occurring within 30 days after a surgical operation (or within one year if an implant is left in place after the procedure) and affecting either the incision or deep tissues at the operation site[1]. SSIs impose a substantial burden of morbidity and mortality which in turn imposes a heavy demand on health care resources[2]. In the United States of America, it was estimated that SSIs were associated with an additional 9.7 days in extra hospital stay and extra cost of $20,842 per admission[3]. Studies from Asia show that SSI increase length of hospital stay by an average of 20.7 days with mean extra health care expenditure of $8791 per admission[4]. The economic burden in Africa is largely unknown. Besides the economic burden, patients who develop SSI are twice more likely to die, 60% more likely to spend time in the intensive care unit (ICU) and more than five times more likely to be readmitted to the hospital[5]. The prevalence of SSIs is still significantly high among children in developing countries like Nigeria with a prevalence of up to 14.3% for clean wounds and 24.4% for clean-contaminated wounds[6,7]. The SSI rate following abdominal surgeries is also significantly high in our environment with an overall rate of 23.8% in children[6].

Considering the burden of SSIs, focus on SSI initiatives has shifted from treatment to prevention as 40 - 60% of SSIs are preventable[1]. One of the commonly used operative strategies to reduce SSI is the plastic

Address for Correspondence:

Dr. Chuka Abunike Ugwunne
Paediatric Surgery Unit, Department of Surgery, Nnamdi Azikiwe University Teaching Hospital, P.M.B 5025 Nnewi, Anambra State, Nigeria.
Email: chuksug@yahoo.co.uk

adhesive drape[8]. This was first tested in 1956 by Payne on a cohort of patients undergoing a range of abdominal surgeries[9]. Since then, use of adhesive drapes have become widespread with various modifications made to improve effectiveness such as the iodine impregnated drapes.

For most SSIs, the source of the invading pathogen is the patient's skin[10]. Consequently, preoperative skin preparation is intended to make the skin as free as possible from bacteria that may enter the surgical wound. Although skin disinfection prior to surgery drastically reduces the number of bacteria on the skin's surface, re-colonisation with bacteria from deeper skin layers and hair follicles may occur during operation[11]. Thus, adhesive drapes are used to prevent any contact with unprepared surfaces and also act as a microbial barrier to prevent migration of contaminating bacteria from the skin to the operative site thereby reducing contamination of the surgical wound[12].

Although there is a theoretical plausibility for the use of adhesive drapes, conflicting reports have been published regarding their usefulness in reducing SSIs. Moreover, the use of adhesive drapes have not been tested among children. Therefore, this study was designed to assess the effect of iodine impregnated adhesive drapes on the incidence of SSI following clean and clean contaminated abdominal surgeries in children in Nigeria.

Materials and Methods

The study was a prospective randomized controlled study of children aged 1 month to 18 years who had clean and clean contaminated abdominal surgeries in Nnamdi Azikiwe University Teaching Hospital between October 2018 and September 2019. Following ethical approval from the Research and Ethical Committee of Nnamdi Azikiwe University Teaching Hospital for the study, 120 consecutive patients planned for clean and clean contaminated abdominal surgeries were randomly assigned to two groups; A and B, of 60 each [use of iodine impregnated incise drapes(A) and non-use(B)]. Each group had patients undergoing both clean and clean-contaminated abdominal surgeries. The first patient for each class of wound was selected by simple balloting method by picking from a sealed envelope containing two folded papers containing use and non-use of iodine impregnated incise drape. The next patient was automatically assigned to the alternate group for each class of wound. Patients for which consent was not given by the care-givers, those with immunosuppresion and those who had known allergies to iodine were excluded from the study. Written informed consent was also obtained from all care givers and the child subsequently enrolled into the study once the inclusion criteria were met.

For all procedures strict adherence to aseptic protocol for surgeon preparation was observed. Prophylactic antibiotics using intravenous Ceftriaxone (50mg/kg, not exceeding 1g) and intravenous metronidazole (7.5mg/kg) was given at induction of anaesthesia for patients with clean contaminated wounds. Patients in both groups had preoperative skin preparation with savlon (Cetrimide 0.5% w/w / Chlorhexidine Digluconate 0.1% w/w) and methylated spirit (70% w/w alcohol solution). Gauze squares soaked in savlon was used to thoroughly cleanse the skin twice after which a dry gauze square was used to dry the skin. Then a gauze square soaked in methylated spirit was used to apply methylated spirit to the skin. This was done by starting from the operative site and working outward in a circular motion up to 15-20 centimeters from the operation site.

Cloth side drapes were applied and the operative field dried with a sterile swab. The drying of the alcohol is essential for achieving good adherence of the drape without the edges lifting during the operative procedure. In the patients for whom Iodine impregnated incise drape was allocated; the iodine-impregnated incise drape was then applied over the operative field with adequate tension. The drape was smoothened down, first along the intended incision line and then over the remaining areas. Incisions were made through the drape and the operative procedure was carried out. At completion of the operative procedure and following closure of fascia and subcutaneous tissue, the drape was lifted off from wound edge by about one inch to allow for skin closure, after which wound cleansing and dressing was done.

3M™ Ioban™ 2 REF 6635 ID 70200678848 as used for this study. It is made of a vapour-permeable polyester film coated with a clear acrylate adhesive containing a Polyvinylpyrrolidone complex. This complex consists of N-vinyl-pyrrolidone, iodine (0.117– 0.197 mg/cm2) and sodium iodide, from which free iodine is slowly released for delivery into the skin.

Postoperatively, clean wounds were directly inspected on the fifth day, while clean-contaminated wounds were inspected on the third day. The wound inspection was by a trained research assistant who was blinded to the intervention the patient had. All patients were followed up for at least 30 days at the paediatric surgery out-patient clinic or paediatric surgery ward if still on admission, where wounds would be inspected at weekly intervals or as the need arose. A modification of the Southampton wound infection scoring system was employed for identification and grading of surgical site infections when present[13]. Grade I wound

infection was taken as presence of undue wound redness and swelling, Grade II as discharge of serous or haemoserous fluids from the surgical wound, Grade III as discharge of pus from the wound, and Grade IV as discharge of pus and wound dehiscence. The findings were recorded on a pre-structured pro-forma and kept in a sealed envelope bearing only the patient's initials and hospital number.

Statistical analysis was done using IBM SPSS Statistics V21.0. Results obtained were expressed using tables, charts, and mean±standard deviation where necessary. Pearson chi square and Fishers exact test were used for categorical variables and T-test for continuous variables. Regression analysis was done for predictors of surgical site infections. Statistical significance was inferred at p value of <0.05.

Results

There were a total of 77 males and 43 females. The patients' age ranged between 1 month to 204 months in the non-Ioban™ group and 2 months to 192 months in the Ioban™ group. There was no statistically significant difference in age, weight and duration of surgery between patients in the Ioban™ and non-Ioban™ groups in both clean and clean-contaminated abdominal surgeries as seen in table 1.

Table 1: Age, weight and duration of surgery for patients with clean and clean contaminated surgeries

	Ioban™ group	No Ioban™ group	T	P value
Clean surgeries				
Age (in months)	50.63 ± 34.93	61.67 ± 46.53	-1.039	0.303
Weight (in kg)	17.99 ± 10.55	21.6800 ± 13.54	-1.177	0.244
Duration of surgery (in minutes)	39.43 ± 16.96	47.70 ± 17.10	-1.888	0.065
Clean contaminated surgeries				
Age (in months)	30.84 ± 8.7	51.38 ± 12.27	-1.379	0.173
Weight (in kg)	12.80 ± 1.95	17.86 ± 3.24	-1.354	0.181
Duration of surgery (in minutes)	85.06 ± 8.00	80.07 ± 7.07	0.563	0.576

The most common abdominal condition requiring surgery with clean wounds was inguinal hernias (51.6%). The most common abdominal condition requiring surgery with clean contaminated wounds was ileocolic intussusceptions (55.0%). See table 2 and 3.

Table 2: Indications for clean abdominal surgeries categorised into Ioban and Non-Ioban

Diagnosis	Ioban™		
	No	Yes	P-value
Inguinal hernia	16	15	0.765
	51.6%	48.4%	
Hydrocele	9	10	0.673
	47.4%	52.6%	
Umbilical hernia	5	4	0.981
	55.6%	44.4%	
Supraumbilical hernia	0	1	0.987
	0.0%	100.0%	
Total	**30**	**30**	
	50.0%	**50.0%**	

Table 3: Indications for clean contaminated abdominal surgeries categorised into Ioban™ and Non- Ioban™ groups

Diagnosis	Use of Ioban™		
	No	Yes	P value
Ileocolic intussusceptions	15 (41.9%)	18 (58.1%)	0.443
Obstructed inguinal hernia	7 (53.8%)	6 (46.2%)	0.981
Uncomplicated appendicitis	4 (57.1%)	3 (42.9%)	0.847
PUJ obstruction	1 (33.3%)	2 (66.7%)	0.921
Renal injury	1 (50.0%)	1 (50.0%)	1.00
Splenic injury	2 (100.0%)	0 (0.0%)	0.968

The most common clean abdominal surgery performed was herniotomy (48 out of 60). The other clean abdominal surgeries were herniorrhaphies (12 out of 60). While laparotomy with open reduction of intussusception was the most commonly performed clean contaminated abdominal surgery (33 out of 60). See tables 4 and 5.

Table 4: Clean abdominal surgeries performed

	Surgery performed		Total
Diagnosis	Herniorrhaphy	Herniotomy	
Inguinal hernia	2	29	31
Hydrocele	0	19	19
Umbilical hernia	9	0	9
Supraumilical hernia	1	0	1
Total	**12**	**48**	**60**

Table 5: Clean contaminated abdominal surgeries performed

	Surgeries Performed						
	AP	OR	GH	N	P	S	Total
Diagnosis							
ICT	-	33	-	-	-	-	33
OIH	-	-	13	-	-	-	13
UA	7	-	-	-	-	-	7
PO	-	-	-	-	3	-	3
RI	-	-	-	2	-	-	2
SI	-	-	-	-	-	2	2
Total	7	33	13	2	3	2	60

Key:

UA	Uncomplicated appendicitis	AP	Appendectomy
ICT	Ileocolic intussusception	OR	Open reduction
OIH	Obstructed inguinal hernia	GH	Groin exploration and herniotomy
PO	PUJ obstruction	P	Pyeloplasty
RI	Renal injury	N	Nephrectomy
SI	Splenic injury	S	Splenectomy

Looking at the clean abdominal surgeries, 3 (10%) of the patients in the Ioban™ group developed surgical site infections while 4 (13.3%) of the patients in the non- Ioban™ group developed surgical site infections. There was no statistical significant difference between the 2 groups with a P-value of 0.668. For the clean contaminated abdominal surgeries, the SSI rate in the non- Ioban™ group was 26.6% while the SSI rate in the Ioban™ group was 13.3%. There was no statistical significant difference between the 2 groups with a P-value of 0.155. (Table 6)

Table 6: Relationship between use of Ioban™ and surgical site infection

Class of surgery	Group	SSI		X2	P value
		No (n=53)	Yes (n=7)		
Clean surgery	No Ioban	26 (49.1%)	4 (57.1%)	0.162	0.668
	Ioban	27 (50.9%)	3 (42.9%)		
		No (n=48)	**Yes (n=12)**		
Clean contaminated surgery	No Ioban	22 (45.8%)	8 (66.7%)	2.019	0.155
	Ioban	26 (54.2%)	4 (33.3%)		

Using a multivariate analysis to determine predictors of surgical site infections in clean and clean contaminated abdominal wounds, the use of Ioban™ was not found to be a predictor of SSI. The only predictor of SSI for the variables looked at was bowel involvement in the clean contaminated abdominal surgeries with P value = 0.006. (Tables 7 and 8)

Table 7: Predictors of SSI in clean abdominal surgeries

Factors	P value	Odds ratio	95% C.I.for EXP (B)	
			Lower	Upper
Surgeon cadre	.265	2.606	.483	14.060
Use of Ioban™	.647	1.460	.289	7.375
Sex	.700	.632	.061	6.510

*all the surgeries in this group were less than 120 minutes duration

Table 8: Predictors of SSI in clean contaminated abdominal surgeries

Factors	P value	Odd ratio	95% C.I.for EXP (B)	
			Lower	Upper
Surgeon cadre	.816	.813	.142	4.646
Bowel involvement	.006	11.611	2.011	67.018
Use of Ioban™	.123	3.700	.701	19.536
Sex	.830	.802	.107	6.007
Duration*	.800	1.287	.183	9.063

*duration of surgery less than or more than 120 minutes were used

Discussion

This study was a prospective randomised controlled study to determine the effect of iodine impregnated incise drapes (3M™ Ioban™ 2) on the incidence of SSI following clean and clean contaminated abdominal surgeries in children. This study showed that 13.3% of patients in the non- Ioban™ group who had clean surgeries developed SSI. This SSI rate for clean abdominal surgeries in this study is similar to 14.3% reported by Ameh et al[6] for clean surgeries in general among children in Nigeria. Although the SSI rate is slightly lower (10%) for those in the Ioban™ group for clean surgeries, there was no statistical significant difference between the two groups in this study with a P-value of 0.668.

Theoretically, Ioban™ prevents surgical site contamination in 2 ways: iodine provides continuous antimicrobial activity against skin flora, and the adhesive drape sticks to wound edges and forms a barrier that prevents skin flora from entering the incision. Indeed, reduction in surgical site contamination with the use of Ioban has been demonstrated by Fairclough et al[14]. In his study wound contamination dropped from 15% in control group to 1.6% in the Ioban group with P-value <0.001. Dewan et al[15] also demonstrated statistically significant reduction in wound contamination with Ioban for abdominal surgeries. It was thus expected that Ioban™ should reduce wound contamination and by extension surgical site infection in clean surgeries where the source of contamination is the patient's skin. However this study did not show such reduction in SSI

rate. This is similar to findings in another randomised controlled study where iodine impregnated incise drapes was used for clean abdominal surgeries[15]. Dewan et al[15] reported a SSI rate of 4.8% without use of iodine impregnated incise drapes and 5.5% with the use of iodine impregnated incise drapes for clean abdominal surgeries. This was not statistically significant, which is similar to findings in this study. Also Swenson et al[16] in his study on the use of Ioban for the prevention of mesh infection after ventral hernia repair reported an SSI rate of 15% vs 12.1% for non-Ioban™ and Ioban™ groups respectively. Although his study was retrospective, there was no statistical significant difference between SSI rates in the two groups with a P-value of 0.36. This is similar to the finding in this study.

Since Ioban™ is known to reduce wound contamination, which as demonstrated by this study does not translate to a reduction in SSI, it suggests that the events following wound closure continue to be important and may account for the similarity in SSI rates with or without the use of Ioban™. It is however possible that this tangential reduction in SSI rate observed in this study may show statistical significant difference if a larger sample size is used as with the low infection rate for clean surgeries, several hundred cases would be required to show any difference. Parks[17] calculated that a sample size of at least 10,000 is required in order to confirm the efficacy of iodine-impregnated incision drape due to the low rate of SSI in clean and clean-contaminated surgery.

As expected, the SSI rate for clean contaminated abdominal surgeries was higher when compared to the clean abdominal surgeries. The SSI rate in the non-Ioban™ group was 26.6% which is similar to SSI rates for clean contaminated surgeries in general among children from developing countries like Nigeria and Mexico with rates of 19.3% and 24.4% as reported by Ameh et al[6] and Porras-Hernández et al[18], respectively. Though the SSI rate for the Ioban™ group in the clean contaminated surgeries was half the rate for the non-Ioban™ group i.e 13.3%, there was no statistical significant difference between the 2 groups with a p-value of 0.155. This finding is similar to other reports on the use of iodine impregnated incise drapes for clean contaminated abdominal surgery. Dewan et al[15] reported SSI rates of 6.9% and 6.4% for non-Ioban and Ioban groups respectively following clean contaminated abdominal surgery which was not statistically significant. Also Ward et al[19] with the use of OPSITE (non-antimicrobial incise drape) for caesarean section reported an SSI rate of 10.1% and 11.1% in the non-incise drapes and incise drapes groups respectively which was not statistically significant. The possible explanation for this may be that organisms responsible for SSI in clean contaminated abdominal surgeries could be from a hollow viscus encountered during the surgery, and as such use of iodine impregnated incise drapes would not be beneficial in preventing SSI in such class of wound. However, assessment for SSI in this study was done by the modified Southampton wound grading system which is a clinical assessment method requiring no wound culture, hence the offending organisms in the detected SSI could not be corroborated to either skin or bowel flora although Dewan et al[15] reported in his study that the initial organisms cultured in the contaminated wound frequently bore little relationship to those observed once the wound became infected and particularly following the use of the iodine impregnated incise drape.

The use of iodine impregnated incise drapes was not a predictor of surgical site infection for both clean and clean contaminated surgeries. The anticipated benefit of the use of iodine impregnated incise drapes for abdominal surgeries on the surgical site infection rates was not observed. This is so, even in the more specific instances in which a benefit could be expected, namely in clean wounds where only skin organisms are expected to be a factor and in long procedures where regenerating skin organisms occur in greater numbers with time. Based on this study, the use of iodine impregnated incise drapes is not recommended as an SSI preventive measure for clean and clean contaminated abdominal surgeries in children. There is however the need for a large randomised control trial (possibly multi-centred) to be carried out to determine whether iodine impregnated incise drapes do prevent or reduce SSI rates following clean and clean contaminated abdominal surgeries in children.

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Conflict of interest: Nil
Source of funding: Nil

Date received: Oct 23, 2024
Date accepted: Dec 20, 2024