

Efficacy of barrier wound protection (using wound protector/retractor[Alexis]) in the prevention of surgical site infections in open abdominal surgeries

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Abstract

Background : Surgical site Infections (SSI) remains an important complication, only secondary to urinary tract infections as the common nosocomial infection in hospitalized patients. This leads to prolonged convalescence, physical and financial burden to patient and hospitals. Alexis wound protector/retractor is identified as a dual role retraction device that also may result in reduced enteric bacterial colonization of the surgical incision site during gastrointestinal surgery. The goal of this study was to evaluate the effectiveness of Alexis wound retractor in prevention of surgical site infections .**Methods:** Randomized Prospective study of 60 patients undergoing laparotomy/laparoscopic assisted surgeries, divided into two groups, one group using wound protector and the other group without using wound protector, and study the outcome in terms of post surgical incisional wound infection in both groups.**Results :** Use of Alexis wound retractor reduced the rate of surgical site infections across all sub groups considered . Statistically significant difference in the two arms of this study was found in wound infection rate in patients undergoing surgery for malignant conditions . Marked reduction in surgical site infection was also found in surgeries lasting for less than 180 minutes(no infections in the Alexis group) , in obese patients (14 % vs. 44 % { Alexis vs conventional group } , p value = 0.07) , in emergency surgeries (no infections in the Alexis group).**Conclusion :** Use of Alexis wound retractors reduces surgical site infection in laparotomy wounds and requires further evaluation for its application as a means of reducing surgical site infections .

Keywords : Wound, infection, surgical.

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Introduction

Surgical site Infections (SSI) remains an important complication, only secondary to urinary tract infections as the common nosocomial infection in hospitalized patients. This leads to prolonged convalescence, physical and financial burden to patient and hospitals. The reported incidence is 3% to 20%. There is also significant morbidity associated with SSI, a large number of patients develop long-term disabilities as a result of poor wound healing and overt tissue destruction. The economic cost of surgical site infections is high.SSI is an infection that occurs in the operative field following a

surgical intervention. It includes both incisional SSI and organ space SSI.Incisional SSI is subdivided into superficial and deep SSI, depending upon whether the infection is limited to the skin and subcutaneous tissue only or extends into the deeper tissues, such as the fascial and muscular layers of the body wall. Organ-space SSI is an infection that occurs within the operative field other than where the body wall tissues were incised.The CDC (Centre for disease control and prevention) summarized risk factors for SSI as follows1 (Table 1)

Table 1 : Risk factors for Surgical Site Infections

Patient related	Operation
Age	Duration of surgical scrub
Nutritional status	Skin antisepsis
Diabetes mellitus	Preoperative shaving
Smoking	Preoperative skin preparation
Obesity	Duration of operation
Coexisting infections at remote body site/ Malignancy	Antimicrobial prophylaxis
Colonization of microbes	Operating room ventilation
Altered immune response	Inadequate sterilization of instruments
Length of preoperative stay	Foreign material in the surgical site

The impact of these risk factors can be seen in information provided by the National Healthcare Safety Network (NHSN) about SSI rates

for various operative procedures performed in2006-2007. Selected data from this publication are summarized as[1,2],(Table 2) .

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Table 2: Impact of risk factors on development of surgical site infections

Procedure	Number of risk factors			
	0	1	2	3
Appendectomy	1.49		3.49	
Bile duct, liver or pancreatic surgery	8.77		16.34	
Breast surgery	0.8	2.74		
Colon surgery	4.18	6.07	8.01	10.86
Gastric surgery	1.84		4.86	
Herniorrhaphy	1.02	2.47	4.36	
Peripheral vascular bypass surgery	2			
Small bowel surgery	2.62	6.31		

Multivariate analyses have identified large numbers of specific risk factors which place the patient at higher risk of developing a SSI:

- Patient characteristics, such as increased age or the presence of a remote infection at the time of the operation
- Aspects of preoperative, intraoperative, and postoperative management, such as delayed delivery of prophylactic antibiotics or flash sterilization of surgical instruments.

Interventions to prevent SSI are based on knowledge of various risk factors that predispose a patient to develop such an infection and understanding of the microbiology of SSI. Interventions to prevent SSI are based on knowledge of various risk factors that predispose a patient to develop such an infection and understanding of the microbiology of SSI. General measures to prevent SSI can be organized into those directed at the patient's preoperative risk factors and those that relate to perioperative management of the patient. With respect to the latter, considerations include the patient's and the operative team's preparations for surgery, the operating room environment, intraoperative techniques, and other aspects of the patient's intraoperative and postoperative cares. For the interventions based on peri-operative approaches, there are not many conclusive and complete data available. Preoperative hair removal by shaving compared to depilation has been at times found to increase SSI rates. Preoperative showering with antiseptic agents such as chlorhexidine has not been recommended. However appropriate skin preparation at the time of the operative procedure with an antiseptic agent is a well-established preventive measure. Acceptable antiseptic agents include alcohol, chlorhexidine, iodine and iodophors, some of which now have been reformulated for longer duration of action. However available data have not conclusively shown that any of these agents are superior to other. Regarding postoperative management, most important detail is to monitor the surgical wound for the development of SSI. Early

management of an infected wound helps avoid more major subsequent complication. Preoperative skin preparation consists of many things like scrub bath using simple/antiseptic soap; repeated detergent and antiseptic painting; hair removal by clippers, razor shaving or depilatory cream; covering local area with sterile bandage or steri drapes etc.

Other ways of preventing wound infections

Antibiotic prophylaxis: Use of appropriate iv antibiotics pre-operatively reduces the chances of post-operative incidence of SSI.

Perioperative sugars: Good control of blood sugars in peri-operative period also decreases the incidence of SSI.

Gastrointestinal surgery is high risk for surgical site infection (SSI), with as many as 25% of patients undergoing colorectal surgery developing SSI [3]. Subsequent prolonged inpatient admission, antibiotic use and slower recovery times are detrimental to patients and costly[4]. Intraoperative technique and perioperative procedures are important for the prevention of SSI [5]. Alexis wound protector/retractor is identified as a dual role retraction device that also may result in reduced enteric bacterial colonization of the surgical incision site during gastrointestinal surgery. The enteric organisms were cultured twice as often from the inside surface of the retractor compared with the outside surface of the retractor. Reduced colonization of surgical incision site by enteric bacteria due to the use of a plastic wound retractor should result in a reduction in SSI (surgical site infection) following gastrointestinal surgery[6]. The Alexis wound protector/retractor provides 360 degree of circumferential, atraumatic retraction, while maintaining moisture at the incision site and reducing superficial surgical site infection following colorectal surgery. The self-retaining design of the Alexis wound protector/retractor effectively holds the incision site open, allowing the surgeon to easily access the operative field and maximise surgical resistance[7].



Fig 1: Alexis wound retractor

The Alexis plastic ring wound retractor/protector facilitates access to the abdominal cavity, particularly during minimally invasive surgery. Other reported uses include gradual closure of gastrochisis in

paediatric patients, intravaginal use in vaginal hysterectomy, and stoma creation in obese patients[8]. Enteric bacteria commonly cause surgical site infections after visceral surgery[9]. Minimizing contact

between the surgical incision site and enteric bacteria should reduce surgical site infections as intraoperative bacterial exposure is associated with post operative infection[10]. While not its primary function, the Alexis wound retractor might provide a barrier to

bacterial contamination. However, studies of similar interventions have yielded surprising results; a Cochrane review suggested that non-iodophore impregnated adhesive plastic wound drapes may increase the rate of wound infection[11].

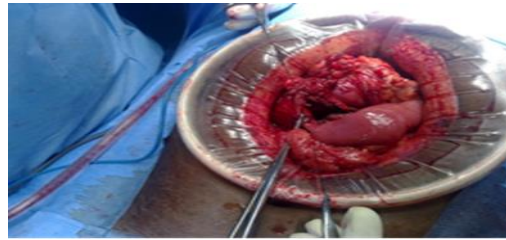


Fig 2: Intra operative pic of alexis wound retractor

Aim: Aim of this study is to examine the efficacy of barrier wound protection using wound protector/retractor [Alexis] in the prevention of surgical site infections in open / laparoscopic converted to open abdominal surgeries

Objective: Objective is to study the rate of surgical site infection using Alexis barrier wound retractor / protector as compared to conventional open surgeries without using barrier wound protection.

Material and Methods

This is a randomized prospective study of 60 cases which were admitted and operated at our hospital .

Material used: Alexis wound retractor/protector (APPLIED MEDICAL Rancho Santa Margarita, CA 92688 USA). Small, Medium, large and extra-large sizes are included.

Method

Randomized Prospective study of 60 patients undergoing laparotomy between May 2014 and May 2015 , divided into two groups, one group using wound protector and the other group without using wound protector, and study the outcome in terms of post surgical incisional wound infection in both groups. Patients were followed up for a period of 30 days post operatively. Series of 60 patients in that odd numbers were in the Alexis wound retractor group and even numbers in conventional group.

Inclusion criteria

1. All age groups above 20 years.
2. Both sexes

3. Co morbidities – DM, Obesity.

4. Open abdominal surgeries.

5. Laparoscopic assisted surgeries.

6. Laparoscopic abdominal surgeries converted to open abdominal surgeries

7. Both elective and emergency laparotomy are included in the study group. Emergency cases included in the study are the ones without peritonitis. eg, Acute intestinal obstruction.

Exclusion criteria

1 .Emergency laparotomies with abdominal sepsis (peritonitis) are excluded.

2. Surgeries associated with hernia mesh repair.

3. Class 4, dirty infected wounds

Patients are given routine preoperative antibiotic (Cephalosporin), during induction.

Postoperative follow-up of the wound is done as follows:

• First follow up: After 72 hrs. of operation (3rd post-operative day).

• Second follow up: at 7 days of operation.

• Last follow up: at 30 days of operation.

Results

The patients in both groups (Alexis and non Alexis) were matched for specific variables and rates of wound infection within these sub groups were compared .

1. Age of the patient (Table 3)

The age distribution of patients enrolled in this study is as follows -

Table 3 : Age distribution of patients enrolled in this study

Age of the Patients	Total no	%
20 to 40 Years	15	25%
41 to 60 Years	22	37%
60 Years and above	23	38%
Total	60	100%

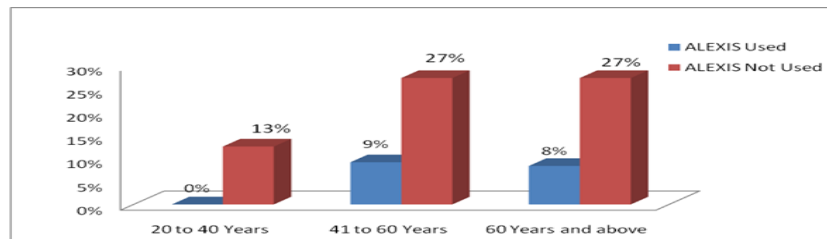


Fig 3: Rates of wound infection in Alexis vs. Non Alexis groups across different age groups. There were no wound infections in patients between 20 – 40 years of age in the Alexis group

In our study the incidence of infection is lesser for the Alexis wound protector group compared to the conventional group (no Alexis used).

The incidence of wound infection was 9 % in the age group 41 to 60 years and 8 % in 60 years and above (for the Alexis wound protector

group) as compared to 27% in the age group 41 to 60 years and also above 60 years (in the conventional group).

2. **Gender of the patient** :Of the patients enrolled in the study 43% were male and 57% were female .In our study, there is

decreased incidence of surgical site infection in both male and female in the Alexis wound protector group as compared to conventional group.(Figure 4)

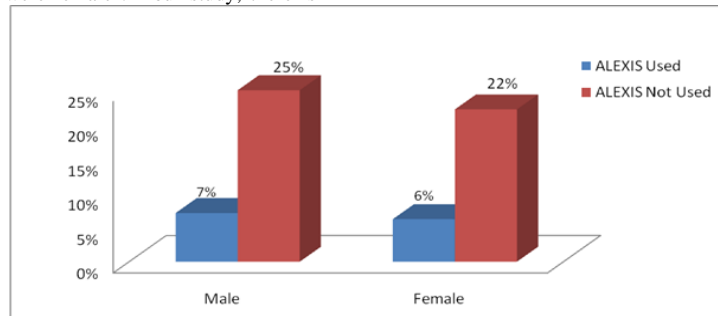


Fig 4: Rates of wound infection in male vs. female patients in Alexis and Non Alexis groups

3. **Body Mass Index of the patient (BMI)**:73% of the patients in this study had a BMI of less than or equal to 25 (non obese) and 27% had a BMI of more than 25 (overweight / obese) . There is decreased incidence of surgical site infection in both non obese and obese patients in Alexis wound retractor group. In

patients with BMI more than 25 the incidence of wound infection in the Alexis wound retractor group was 14% as compared to conventional group which is 44%.(P value is 0.07 which is statistically significant at 90% confidence interval). (Figure 5)

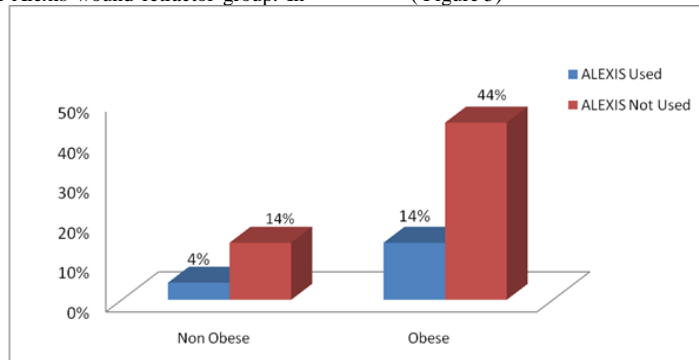


Fig 5:Rates of wound infection in obese patients showed marked differences in the Alexis vs. Non Alexis groups

4. **Diabetics v/s Non diabetic patients** :In our study group, 57% were diabetics and 43% were non diabetics.In our study, there is decreased incidence of surgical site infection in diabetes in Alexis group(6%) as compared to conventional group which is 29%.(Figure 6)

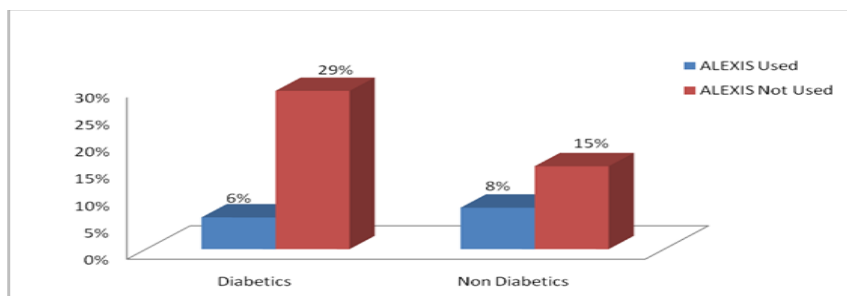


Fig 6:Rates of SSI in diabetics vs. non diabetics in the Alexis and non Alexis groups

5. **Smokers v/s Non smokers** :75% of patients enrolled in the present study were non smokers , 25% were smokers . In our study, there is decreased incidence of surgical site infection in smokers (13% v/s 43%)and non smokers (5% v/s 17%)in Alexis group compared to the conventional group . (Figure 7)

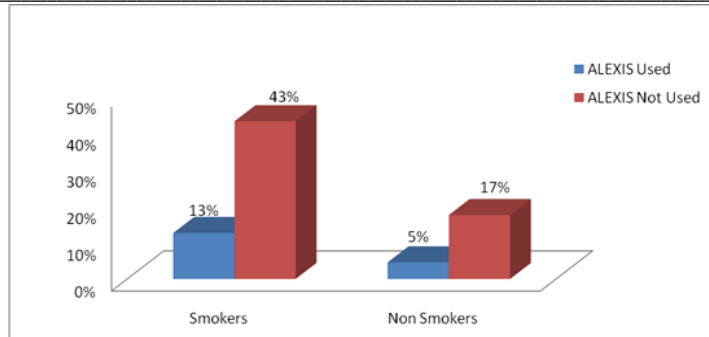


Fig 7: Rates of wound infection in smokers vs non smokers in the Alexis and non Alexis groups

6. **Duration of Surgery** :47% of the patients in this study had surgeries lasting less than 180 minutes , 53% of patients had surgeries lasting more than 180 minutes . There was a decrease in the incidence of SSIs with the use of Alexis wound retractor in both groups .There were no cases with SSI in patients undergoing surgery lasting less than 180 minutes in the Alexis retractor group .(Figure 8)

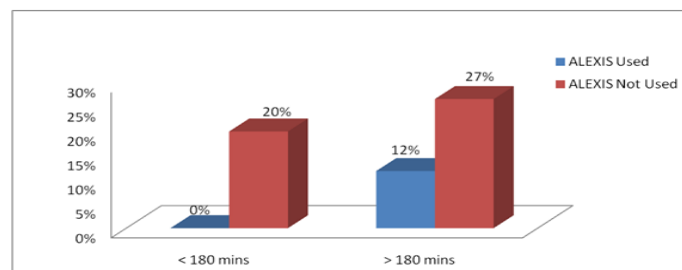


Fig 8: There were no cases of wound infection in surgeries lasting less than 180 minutes was zero in the Alexis group .

7. **Elective and Emergency surgeries** :Nine patients underwent emergency laparotomy in this study (15%) and 51 patients were taken up for elective surgery (85%) . In our study there were no SSIs in the Alexis wound retractor group for emergency cases (compared to 25% in the conventional group) .

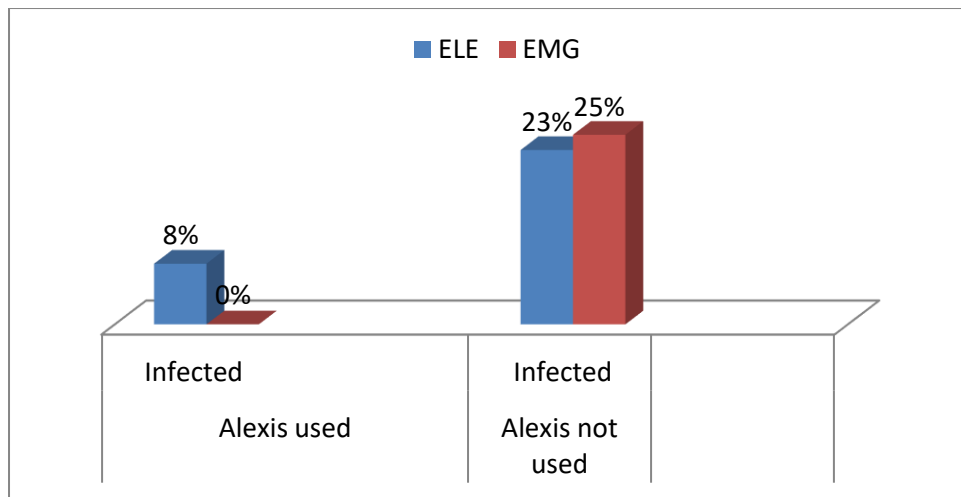


Fig 9: Rates of wound infection in elective and emergency cases in the Alexis and conventional groups

8. **Surgeries for malignancies** :In our study, there is decreased incidence of surgical site infection in surgeries for malignancies in Alexis group which is 8% as compared to conventional group which is 40%. The difference in the incidence of SSI is statistically significant(P value is 0.03).(Figure 10)

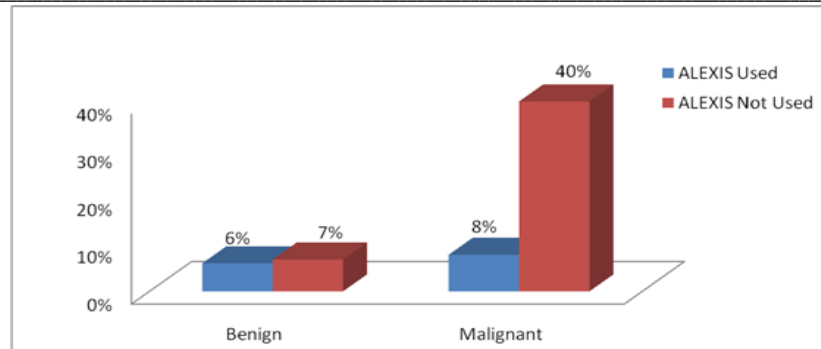


Fig 10: There is a statistically significant difference in the rate of wound infection between Alexis and conventional group in surgeries for malignancies

In our study, overall there is 7% incidence of surgical site infection in Alexis group as compared to conventional group which is 23%. The p-value in this case is 0.071 which represents a significant difference in the wound infection rates between the Alexis vs. conventional group at a 90% confidence interval. Larger studies would probably validate these findings.

Discussion

Present study comprised of 60 patients in the department of surgery at our hospital, who underwent emergency/elective abdominal surgery during the time period of May 2014 to May 2015 to compare the rate of surgical site infection (SSI) using barrier protector as compared to conventional surgeries. Our study concludes that use of Alexis wound retractor helps in reducing surgical site infection in open abdominal surgeries when compared to conventional open surgeries without using barrier wound protection. This is probably due to minimizing contact between the wound edge and the abdominal cavity by a plastic wound retractor, which would be expected to reduce exposure of the incision site to enteric bacteria intraoperatively may translate into reduced SSI [12]. Use of Alexis wound retractor reduced surgical site infections across all the subcategories included in the study. In some groups the use of Alexis wound retractor / protector lead to (statistically) significant lowering of wound infection rates (overweight / obese patients [BMI > 25], patients undergoing surgeries for malignancies). In patients between 20 to 40 years of age and in surgeries lasting less than 180 minutes the Alexis group did not have any wound infections. In our present study, the incidence of surgical site infection rises with age in both Alexis group and conventional group, with a peak incidence in patients above 40 years. Elderly patients have decreased immune resistance, impaired healing process and poor compliance compared to young age; hence the incidence of surgical site infection is more in elderly age group. Here also it is shown that incidence of surgical site infection is less in Alexis group when compared to conventional group however the difference was not statistically significant [13,14]. In both the genders, the use of Alexis wound retractor decreased the incidence of wound infection (7% in male, 6% in female) when compared to conventional group where Alexis retractor was not used (25% in male, 22% in female). A statistically significant difference (at 90% confidence interval) was observed in the incidence of surgical site infection among Alexis v/s conventional groups in overweight / obese patients. There is an increased incidence in the conventional group when compared to Alexis group (44% v/s 14%) where barrier wound protection was used (P value is 0.07) [15,16]. The incidence of surgical site infection is more among diabetics in conventional group, whereas among Alexis group the incidence of wound infection among diabetics is less. In our study, the incidence of rate of wound infection is more among smokers in both Alexis and conventional group. Compared to

conventional group the incidence of surgical site infection is less in the Alexis group [17]. In our study, the incidence of surgical site infection is more among surgeries lasting for more than 180 minutes in both Alexis wound protector and conventional group. The factors which were incriminated were the onset of fatigue resulting in a decline of aseptic measures and an increased risk of bacterial contamination with increasing duration of surgery [18,19]. In comparison with conventional group, there is decreased incidence of rate of surgical site infection in Alexis wound protector group. Incidence of surgical site infection is less in the Alexis group for both elective and emergency cases when compared with conventional group. Among the Alexis group, the incidence of SSI is lesser in emergency surgery compared to elective cases. The probable cause could be factors like antibiotics used, skin preparation, which was done just prior to surgery in emergency surgery which reduced the probability of infection. Among the Alexis group, the incidence of SSI is lesser in emergency surgery compared to elective, the probable cause could be factors like antibiotics used, skin preparation, which was done just prior to surgery in emergency surgery which reduced the probability of infection. Also the patients undergoing emergency surgery commonly had benign conditions with duration of operation lasting less than 180 minutes, as compared to the elective cases where a greater proportion of cases had a longer duration of surgery (more than 180 min). Among conventional group, the incidence of SSI among elective and emergency surgery is almost equal.

In our study, there is statistically significant (P value 0.03) difference in the incidence of surgical site infection among Alexis and conventional group in patients undergoing laparotomy for malignant conditions, with decreased incidence of SSI in Alexis group (8%) where barrier wound protection was used in comparison with conventional group without Alexis wound retractor (incidence is 40%) [20,21].

Conclusion

In this study, Alexis wound protector has been useful in the reduction of rate SSI in comparison with conventional group where barrier protector was not used. Use of Alexis wound retractor leads to significantly decreased wound infection rates in patients undergoing laparotomy for malignant conditions. Use of Alexis wound protector / retractor also resulted in markedly reduced surgical site infections in patients with BMI >25, in younger patients (< 40 years), in surgeries lasting less than 180 minutes and in emergency laparotomies, however larger studies are required to validate the statistical relevance in these groups. In view of the limited number of cases in this study it will require validation from larger studies.

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