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## 2 **Abstract**

3 **Background:** Delayed sternal closure (DSC) is a well-established surgical intervention  
4 following complex congenital cardiac surgeries mitigating postoperative haemodynamic and  
5 respiratory instability. It is mostly used in neonates requiring prolonged cardiopulmonary  
6 bypass, aortic cross-clamp times or deep hypothermic circulatory arrest, predisposing to  
7 myocardial oedema or bleeding. Our study evaluates morbidity and mortality after DSC in  
8 neonates including superficial, deep sternal wound infections and requirement of surgical  
9 debridement.

10 **Methods:** Retrospective review of neonates who underwent DSC after cardiac surgery in a  
11 single centre from 2015 to 2021.

12 **Results:** 187 neonates were identified. Mean age and weight were  $12.8 \pm 6.8$  days and  $3.3 \pm$   
13  $0.5$  kg, respectively. Mean days of opened chest were  $3.8 \pm 5.8$  days. Two neonates (1.07%)  
14 required sternal wound debridement, whilst 19 cases (10.2%) had superficial wound infections.  
15 Mean ICU and hospital stay were  $12.8 \pm 16.6$  and  $25.9 \pm 36.9$  days. 30-days mortality occurred  
16 in 9 cases (4.8%). Univariate analysis indicated that DSC days ( $p= 0.01$ ), ECMO ( $p= 0.000$ ),  
17 aortic cross clamp time ( $p= 0.007$ ) and CPB time ( $p=0.006$ ) to be associated with 30-days  
18 mortality, whilst in multivariable analysis, only ECMO was significant ( $p= 0.002$ ). RACHS-1  
19 score was the only independent risk factor for sternal wound infection in univariate analysis ( $p$   
20  $=0.019$ ) and multivariable analysis ( $p=0.05$ ).

21 **Conclusion:** DSC is a safe therapeutic option following complex neonatal cardiac surgery,  
22 where cardiac compression by sternal approximation is not tolerated because of, myocardial  
23 oedema, haemodynamic instability or coagulopathy. Higher RACHS-1 score was associated  
24 with greater incidence of sternal wound infections.

1

## 2 **Introduction**

3 Delayed sternal closure (DSC) is a widely recognised surgical intervention aimed at mitigating  
4 postoperative haemodynamic and respiratory instability in paediatric patients following  
5 complex cardiac surgery [1]. Approximately 10% of paediatric cardiac patients leave the  
6 operating room with an open chest, with subsequent sternal closure performed after an average  
7 duration of three days [2–4].

8 It is most frequently indicated in complex cases involving prolonged cardiopulmonary bypass  
9 and aortic cross-clamping, which can potentially lead to intraoperative bleeding and  
10 myocardial oedema [5]. In such circumstances, sternal closure can trigger haemodynamic  
11 instability with reduction in cardiac output and diastolic filling [5]. Delayed chest closure can  
12 improve morbidity and mortality for patients following complex paediatric cardiac operations,  
13 by preventing the onset of haemodynamic instability.

14 However, DSC may predispose patients to sternal wound infections (SWI) and mediastinitis  
15 [6-9]. SWIs can be categorised into two types: superficial SWIs, managed conservatively with  
16 antibiotics, and deep SWIs which require surgical debridement. Albeit rare, severe  
17 complications such as sepsis, can be life-threatening [6]. Moreover, mortality rates in this  
18 critically ill patient subgroup vary considerably, ranging from 8 % to as high as 34% [1-6].

19 Considering the pros and cons of DSC, a lack of consensus exists within the literature  
20 concerning the indication for or timing of sternal closure in these patients. Moreover, different  
21 clinical series report variable morbidity and mortality rates associated with this procedure. A  
22 prevalence of 3.5-18.0 % for SWIs following delayed sternal closure has been documented in  
23 the literature [2–4, 6–15]. This retrospective review aims to evaluate the morbidity and  
24 mortality following delayed sternal closure in the neonatal population, focusing on the

1 occurrence of superficial and deep sternal wound infections and the requirement of surgical  
2 debridement.

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#### 4 **Material and methods**

##### 5 **Study design and patient population**

6 This study has been approved by Liverpool John Moores University Ethical committee (UREC  
7 reference number: 25/NAP/001). A retrospective data collection was performed for neonates  
8 who underwent DSC following congenital cardiac surgery via sternotomy from 2015 to 2021,  
9 at Alder Hey Children’s Hospital, Liverpool, United Kingdom. Patients who are over 28 days  
10 of age and patients with incomplete data were excluded.

11 Variables including indication of DSC, time to sternal closure, mean paediatric intensive care  
12 unit (PICU), hospital stay duration, superficial & deep wound infections, 30-day mortality,  
13 sepsis and surgical risk according to the Risk Adjustment for Congenital Heart Surgery  
14 (RACHS-1) score, need for extracorporeal membrane oxygenation (ECMO) were extracted  
15 from our database. Data relating to incidence of SWI, surgical intervention and 30-day  
16 mortality were double checked by another author.

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##### 18 **Endpoints**

19 The primary endpoints of this study were the superficial and deep sternal wound infection and  
20 mediastinitis rates with the need for sternal wound debridement rate. Superficial SWIs were  
21 defined as inflammatory changes confirmed with wound swabs. Deep SWIs were confirmed if  
22 the muscular layers were affected. Mediastinitis is defined as a positive pathogen identified by  
23 culture swabs affecting the mediastinum and the sternum. Secondary endpoints involved

1 evaluating associated morbidity such as sepsis, intensive care and hospital stay duration and  
2 30-day mortality rates.

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#### 5 **Indication for DSC**

6 The decision to delay sternal closure is determined preoperatively for operations like the  
7 Arterial Switch Operation for transposition of the great arteries and the Norwood procedure for  
8 hypoplastic left heart syndrome. In other instances, it is decided intraoperatively in case of  
9 myocardial oedema and myocardial distention from a variety of clinical conditions like low  
10 cardiac output, arrhythmias, respiratory failure needing high ventilation pressures.  
11 Coagulopathy with the need to leave the chest packed with swabs is a further indication or in  
12 patients with postoperative circulatory support through central ECMO. Also, we adopt the DSC  
13 policy in the case of pulmonary artery banding (PAB) for single ventricle circulation or in case  
14 of septal defects (Multiple VSDs, Apical VSD or complete AVSD not closable in conjunction  
15 with hypoplastic aortic arch repair under circulatory arrest), as we have experienced, in such  
16 cases, that the PAB will need further adjustments few days after surgery. We use intravenous  
17 (IV) Cefuroxime (Cephalosporin) during the days of opened chest, and we tend to continue it  
18 for 2 doses after chest closure. In case of cephalosporin or penicillin allergy, we use IV  
19 Teicoplanin plus IV gentamicin as an alternative to cefuroxime and we continue them for 2  
20 doses after chest closure.

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1 **Surgical techniques:**

2 Our approach to open chest treatment encompasses various techniques depending on the  
3 surgeon's preference. In cases who went out of theatre on ECMO, we utilise silastic membrane  
4 that is sutured to the skin with continuous 5/0 polypropylene sutures, then we further cover it  
5 with 2 layers of antimicrobial drape (Ioban 3M).

6 In non-ECMO cases, we utilise different techniques based on the individual surgeon's  
7 preference which can be:

8 1- silastic membrane that is sutured to the skin with continuous 5/0 polypropylene sutures,  
9 then we further cover it with 2 layers of antimicrobial drape (Ioban 3M).

10 2- Direct skin closure using subcuticular Monocryl sutures, leaving the sternal edges open.  
11 Then, covering the wound with sterile dressing.

12 3- Sterile dressings over a small size swab left in the chest.

13 4- Antimicrobial drape (Ioban 3M) alone over the open chest with 1 small swab left inside  
14 the chest.

15 5- Few cases needed the use of sternal bridge to keep the sternal edges apart with a piece of  
16 chest drain tube sutured to the sternal edges to prevent compression to the heart or RV-PA  
17 conduit. Then a silastic membrane is sutured to the skin edges covered by a sterile dressing.

18 Upon chest closure, any dressing is removed in a sterile fashion, to expose the sternum  
19 removing retained swabs, mediastinal cavity washout with warm saline solution, followed by  
20 standard sternotomy closure in layers using 2/0 PDS for the sternum, 3/0 Vicryl for the muscle  
21 and subcutaneous layers, and 5/0 Monocryl for subcuticular skin closure. We do all our chest  
22 closures in ICU including those who need ECMO weaning and decannulation. We do not use

1 GORE-TEX membrane to cover the heart routinely. Its use is a surgeon's preference. In case  
2 of needing to cover the heart or great vessels, suturing a ePTFE 0.1 mm membrane (Gore-Tex)  
3 to the pericardial edges with polypropylene 5/0 interrupted sutures is done at the time of chest  
4 closure in ICU.

5 **Regarding the cases who had sternal wound infection:**

6 Out of the two cases who required wound revision and debridement in the operation room, the  
7 first patient exhibited sternal dehiscence on examination and had positive mediastinal wound  
8 swab cultures. The second patient developed signs of a deep sternal wound infection,  
9 characterised by a high C-reactive protein, pyrexia, positive blood cultures and chest swab  
10 cultures, as well as purulent material on swabs covering the midline sternotomy incision with  
11 sternal dehiscence.

12 However, in cases of superficial wound infection, we managed it conservatively with  
13 antibiotics based on the culture and sensitivity results and regular dressings. If the baby needed  
14 frequent dressing change because of superficial discharge, we tend to use PICO negative  
15 pressure wound dressing and we change it every 5-7 days.

16 **Statistical analysis**

17 Categorical data was reported as frequencies and proportions. Mean and standard deviation  
18 were used to express quantitative data. Univariate and multivariable regression analyses were  
19 conducted to identify risk factors for sternal wound infection and 30-day mortality. The level  
20 of significance was considered at p value < 0.05. Statistical analyses were conducted with  
21 SPSS Version 27.0 (SBSS Inc, Chicago, IL).

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1 **Results**

2 **Demographic data**

3 Over a 6-year period, 1896 patients were identified and screened of which 187 neonates were  
4 included in our patient cohort. Mean age and weight at operation were  $12.8 \pm 6.8$  days and  $3.3$   
5  $\pm 0.5$  kg, respectively. Mean aortic cross clamp time and CPB time were  $102.8 \pm 52.5$  and  $183$   
6  $\pm 81$  minutes, respectively. Mean RACHS-1 Score was  $4 \pm 1.05$ . Arterial Switch Operation,  
7 with or without Ventricular Septal Defect (VSD) repair 70 (37.4%), Hypoplastic Aortic Arch  
8 Repair (HAA) 49 (26.2%), Norwood operation 30 (16.0%) comprised the most frequent  
9 operations performed in the DSC cohort as depicted in *Figure 1*.

10 Mean days of open chest were  $3.8 \pm 5.8$  days. Only 2 patients (1.07%) needed sternal wound  
11 debridement in theatre for deep sternal wound infections, whilst 19 cases (10.2%) had  
12 superficial wound infections managed conservatively with antibiotics. Mean days of wound  
13 infection was  $10.76 \pm 6.65$  days and the 2 cases who needed wound revision and debridement  
14 was at the 7th and 17th day after chest closure.

15 Mean ICU and hospital stay were  $12.8 \pm 16.6$  and  $25.9 \pm 36.9$  days respectively. Pre-operative  
16 ECMO was required in 1 neonate (0.5%). Intra-operative ECMO was required in 6 cases  
17 (3.2%), whilst 21 patients (11.2%) needed post-operative ECMO. 52 cases (27.8%) required  
18 further chest explorations. 30-day hospital mortality occurred in 9 cases (4.8%). 24 neonates  
19 (12.8%) developed sepsis within 30 days of primary operation. Demographic data has been  
20 summarised in *Table 1*.

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## 1 **Regression analysis**

2 Univariate regression analysis showed that the RACHS-1 score ( $p=0.019$ , 95% CI -0.047-  
3 0.178) was found to be significantly associated with sternal wound infections as described in  
4 Table 2. Furthermore, DSC days ( $p=0.011$ , 95% CI -0.19 - -0.003), ECMO ( $p=0.000$ , 95% CI  
5 0.251-0.465), aortic cross clamp time ( $p=0.007$ , 95% CI 0.000- 0.003) and CPB time ( $p=0.006$ ,  
6 95% CI -0.002-0.000) were found to be significantly associated with 30-days mortality, in the  
7 univariate regression analysis, which has been depicted in Table 3.

8 On multivariate analysis, the RACHS-1 score was found to be the one significant independent  
9 risk factor for sternal wound infections,  $p= 0.05$ , 95% CI 0.995-4.012 as described in Table 4.

10 In addition, ECMO was found to be the sole significant risk factor for 30-day mortality,  
11 ( $p=0.002$ , 95% CI 0.000-0.122). Multivariate analysis for 30-day mortality is shown in Table  
12 5.

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## 14 **Discussion**

15 Median sternotomy with delayed sternal closure has become standard practice in selected  
16 subgroup of patients needing to optimise postoperative recovery. This strategy proves  
17 particularly advantageous in case of haemodynamic or respiratory instability, myocardial  
18 oedema and dilation, when coagulopathy and bleeding require packing of the chest or the  
19 necessity for central ECMO support. For some subgroup of patients, the decision of leaving  
20 the chest open is taken preoperatively, like in case of ASO for TGA, or following the Norwood  
21 Procedure for HLHS. In other cases, when is likely that additional procedures need to be  
22 performed, like tightening a PAB, the DSC is adopted. Adopting a DSC policy is not without  
23 risks, for instance patients with prolonged CPB time, low cardiac output, or coagulopathy  
24 needing transfusion are recognised be at higher risk for sternal wound infections [1].

1 Furthermore, SWIs have been associated with longer postoperative stays, as well as increasing  
2 the cost of stay due to the requirement for prolonged ventilation [6].

3 A significant challenge in comparing our findings with existing literature lies in the lack of  
4 standardization in defining infection subtypes. Variability in the criteria used to classify  
5 superficial and deep wound infections across studies introduces potential inconsistencies and  
6 may account for some of the observed differences in reported incidence rates [6-16].

7 There exists a variance in the reported incidence rates of sternal wound infections in patients  
8 with DSC. Some retrospective series have found superficial SWI rates as (6.7-9.7%) and deep  
9 SWIs as (3.9-10.5%), respectively[1, 6, 16]. Whilst others have reported no significant  
10 association between DSC and an increase in surgical site infections. Von Stumm et al described  
11 7.3% superficial SWI rate in a 358 paediatric cohort but no deep SWIs requiring surgical  
12 debridement[1]. Furthermore, Yang et al reported a 9.7% surgical site infection rate in neonates  
13 post DSC, of which there were 28 cases of mediastinitis[16]. Our retrospective study  
14 demonstrates similar superficial SWI rates, 10.2%, whilst our deep SWI rate is considerably  
15 lower, 1.07%.

16 Tabbutt and Özker et al reported a 19% mortality rate following paediatric DSC [6, 17].  
17 Hurtado-Sierra et al reported mortality as 22.4% with patients a RACHS- 1 score  $\geq 3$  posing a  
18 higher risk of mortality [3]. Our study shows a considerably lower 30-day mortality rate of  
19 4.8%. 30-day mortality may be attributed to nosocomial infections. 12.8% of our neonates  
20 developed sepsis within 30 days of admission, significantly lower than Ellassal et al, 54.1% in  
21 a paediatric cohort [18]. Infection rates are reported to be higher in patients with prolonged  
22 ICU stay [18]. Our study depicts an association between prolonged ICU stay and the risk of  
23 SWIs on univariate analysis. Our ICU and hospital stay 12.8 (SD 16.6) and 25.9 (SD 36.9)

1 respectively is higher than other neonatal cohorts; Yang et al report a ICU and hospital length  
2 of stay in their SWI as 11.64 (SD 2.6) and 22.26 ( SD 4.3), respectively[16].

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4 On univariate analysis, cardiopulmonary bypass time, prolonged DSC time and aortic cross  
5 clamp time were significantly associated with 30-day mortality. Cardiac surgery-related  
6 morbidity has been primarily attributed to the use of cardiopulmonary bypass. This can be  
7 explained by the fact that extracorporeal circulation can induce a systemic inflammatory  
8 response, trauma, ischemia and reperfusion injury, endothelial dysfunction, and activation of  
9 the coagulation cascade [19-22]. Prolonged cross-clamp time has also been shown to be an  
10 independent predictor of 30-day mortality in the literature, similar to our findings [25].  
11 Furthermore, aortic cross clamp time of more than 60 mins with a 91.2% higher probability of  
12 sternal wound infections. Our study, on the other hand, did not found such association [16].

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14 Our retrospective study found one significant association between a higher RACHS-1 score  
15 and risk of SWIs on multivariable analysis. The majority of our DSC cohort had undergone  
16 arterial switch operations and hypoplastic aortic arch repairs with high RACHS-1 scores of 4,  
17 similar to several other series [6, 24, 25]. This may be explained as more complex operations  
18 with higher RACHS-1 scores are more likely to lead to myocardial oedema, coagulopathy and  
19 haemodynamic instability, increasing the risk of infection.

20 Application of ECMO was a significant risk factor for 30-day mortality in our multivariable  
21 analysis, similar to previous reports[26]. Gupta et al in a 998 paediatric cohort describe a 48.1%  
22 survival rate to hospital discharge with ECMO, with a mortality rate increasing by 12% every  
23 day after 7 days of veno-arterial ECMO use[26].

1 Timing of sternal closure is still a matter of controversy. Riphagen et al. recommends DSC  
2 within 24 hours to lower rates of nosocomial infections and ventilator associated  
3 complications[24]. However, premature closure of the sternum can lead to repeated DSCs  
4 leading to more deleterious effects than a prolonged period of DSC[7]. Our study reports a  
5 DSC time of 3.8 (SD 5.8) days, comparable to the existing literature averaging at 3 days[17,  
6 18]. Furthermore, our study reports no association between DSC time and risk of SWI. This is  
7 contradictory to previous retrospective studies which reported a higher incidence of infection  
8 with longer periods of open chest[2, 27]. This demonstrates the importance of avoiding  
9 premature closure of the sternum as premature closure may lead to further attempts at  
10 reopening the chest[7, 18].

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## 15 **Limitations**

16 It is important to note that although several retrospective studies have been referenced, their  
17 outcomes cannot be generalised or used as a basis for comparison due to the significant  
18 variance in reported mortality and morbidity. Limitations of our study include it being  
19 retrospective and a single centre. Moreover, different surgical delayed sternal closure protocols  
20 exist within our surgeons' group.

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1 **Conclusion**

2 Delayed sternal closure (DSC) represents an efficacious surgical approach for the management  
3 of complex cardiac surgery in the paediatric population. Reassuringly, our findings reveal  
4 minimal incidence of sternal wound infection associated with delayed sternal closure in these  
5 high-risk cases. High RACHS-1 score was the only independent risk factor for sternal wound  
6 infection in univariate analysis ( $p=0.019$ ) and multivariable analysis ( $p=0.05$ ). DSC facilitates  
7 PAB adjustment in high-risk complex cases. Moreover, DSC allows quick access to initiate  
8 postoperative lifesaving ECMO in this critical group of patients.

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12 No funding was received for this research.

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14 **Competing interests**

15 All authors declare no conflict of interest. No authors have any personal or institutional  
16 financial interests related to any content of this manuscript.

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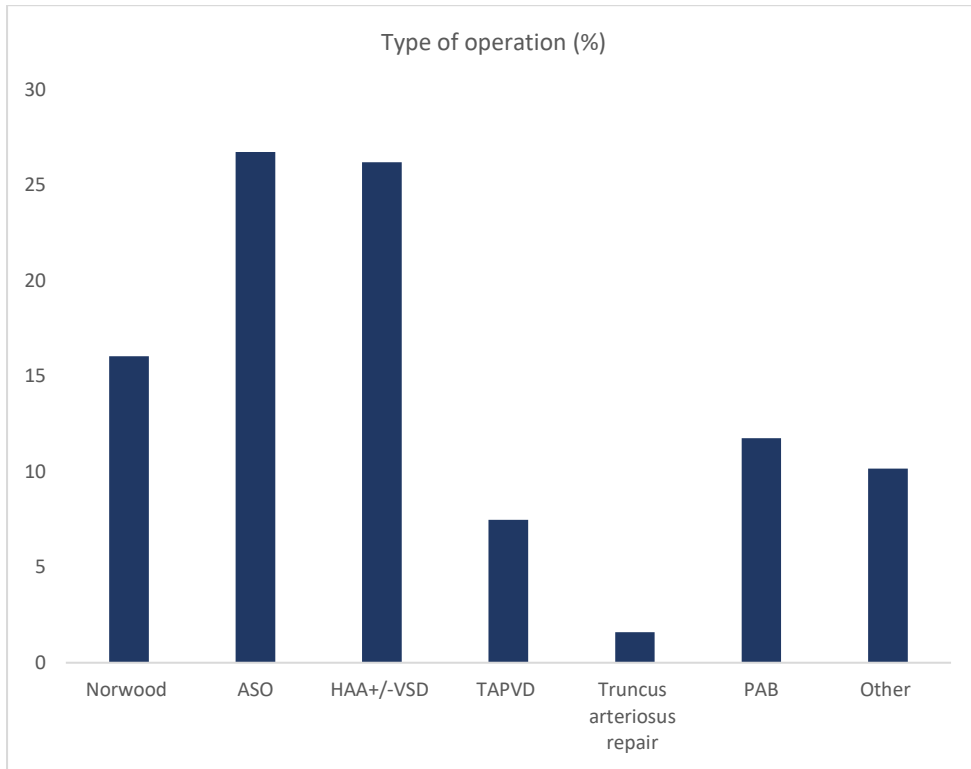
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**Figures:**

**Figure 1:** Types of operations (%). ASO: Arterial Switch operation, HAA +/- VSD: Hypoplastic aortic arch repair with or without ventricular septal defect repair, TAPVD: Total anomalous pulmonary venous drainage repair, PAB: pulmonary artery banding



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2 **Tables:**

3 **Table 1:** Demographic data

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<b>Variables</b>	<b>All cases (n = 187)</b>
<b>Age at operation in days (mean, SD)</b>	12.86 ± 6.45
<b>Female gender (N, %)</b>	59 (31.6%)
<b>RACHS-1 score (mean, SD)</b>	4 ± 1.05
<b>Weight at surgery in kg (mean, SD)</b>	3.33 ± 0.48
<b>ICU stay in days (mean, SD)</b>	12.75 ± 16.57
<b>Hospital stay in days (mean, SD)</b>	25.93 ± 36.88
<b>Time to DSC in days (mean, SD)</b>	3.81 ± 5.80
<b>Pre-operative ECMO (N, %)</b>	1 (0.5%)
<b>Operative ECMO (N, %)</b>	6 (3.2%)
<b>Postoperative ECMO (N, %)</b>	21 (11.2%)
<b>Cardiopulmonary bypass time in minutes (mean, SD)</b>	183.1 ± 80.94
<b>Aortic cross clamp time in minutes (mean, SD)</b>	102.75 ± 52.50
<b>30-day mortality (N, %)</b>	9 (4.3 %)
<b>Sepsis (N, %)</b>	24 (12.8%)
<b>Chest explorations (N, %)</b>	52 (27.8%)

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2 **Table 2:** Univariate logistic regression analysis for dependent variable, sternal wound infections. CI=  
3 confidence interval. The bold values show statistical significance (p <0.05).

Variables	p-value	95% C.I.	
Age at operation (days)	.139	-.006	.007
Sex	.168	-.156	.027
Weight at operation	.462	-.129	.059
ICU days	.987	-.003	.003
DSC days	.074	-.025	.001
ECMO	.299	-.248	.077
RACHS-1 (surgical risk score)	<b>.019</b>	.009	.101
Aortic cross clamp time	.388	-.003	.001
CPB time	.07	.000	.003
Number of chest explorations	.251	-.047	.178

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5 **Table 3:** Univariate logistic regression analysis for dependent variable, 30- day mortality rate. CI=  
6 confidence interval. The bold values show statistical significance (p <0.05).

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Variables	p-value	95% C.I.	
Age at operation (days)	.583	-.005	.003
Sex	.833	-.067	.054
Operative weight	.845	-.068	.056
ICU days	.207	-.003	.001
DSC days	<b>.011</b>	-.019	-.003
ECMO	<b>.000</b>	.251	.465
RACHS-1 (surgical risk score)	.665	-.037	.024
Aortic cross clamp time	<b>.007</b>	.000	.003
CPB time	<b>.006</b>	-.002	.000
Number of chest explorations	.215	-.027	.121

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2 **Table 4:** Multivariable logistic regression analysis for risk factors of sternal wound infections among  
3 neonates undergoing DSC post cardiac surgery. CI= confidence interval. The bold values show  
4 statistical significance (p <0.05).

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Variables	p-value	95% C.I.	
Age at operation (days)	.722	.925	1.120
Sex	.237	.607	7.533
Weight at operation	.49	.158	2.417
ICU days	.82	.964	1.048
DSC days	.211	.768	1.060
ECMO	.232	.450	26.953
RACHS-1 (surgical risk score)	<b>.05</b>	.995	4.012
Aortic cross clamp time	.536	.972	1.015
CPB time	.165	.995	1.030
Number of chest explorations	.347	.526	6.210

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8 **Table 5:** Multivariable logistic regression analysis for risk factors of 30-day mortality among  
9 neonates undergoing DSC post cardiac surgery. CI= confidence interval. The bold values show  
10 statistical significance (p <0.05).

Variables	p-value	95% C.I.	
Age at operation (days)	.359	.666	1.159
Sex	.336	.180	150.776
Operative weight	.629	.023	9.672
ICU days	.116	.680	1.043
DSC days	.824	.648	1.412
ECMO	<b>.002</b>	.000	.122
RACHS-1 (surgical risk score)	.126	.029	1.550
Aortic cross clamp time	.159	.987	1.086
CPB time	.604	.966	1.020
Number of chest explorations	.915	.068	20.174

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