ORIGINAL ARTICLE

Discharge Outcomes of Liveborn Infants With Omphalocele (Isolated Vs Non-isolated)

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ABSTRACT

Introduction: The mortality rate due to omphalocele cases remains high. The presence of other congenital anomalies is believed to be one of the factors causing death in patients with omphalocele. The objective of the study was to determine the influence of other congenital anomalies leading to mortality. **Methods:** We conducted a retrospective cohort study in the neonatal unit of Sardjito General Hospital from March 2008-April 2019. We collected data on factors including sex, mode of delivery, gestational age, birth weight, associated anomalies, management, neonatal complications, need for surgeries, and mortality from our registry and patients' medical records. We then classified the infants into the isolated omphalocele and non-isolated omphalocele groups. Univariate and multivariate analyses were performed to determine the association of congenital anomalies and other confounding factors with mortality. **Results:** We identified 73 omphalocele cases during the study period. The hospital occurrence was 4.3/1000 live-births. We found 45 cases (61.6%) of omphalocele associated with other congenital anomalies including several syndromes (46.7%) such as Patau syndrome and Beckwith-Wiedemann syndrome, congenital heart defects (42.2%), gastrointestinal anomalies (22.2%), neural tube defects (15.6%), cleft palate (11.1%), and syndactyly (0.07%). There was no difference in mortality (25/45 vs 15/28) between the groups (p=0.87). Interestingly, sepsis, pneumonia and gastrointestinal perforation were significantly associated with the survival of infants with omphalocele, with p-value of 0.05, 0.00, and 0.05, respectively. **Conclusion:** Certain complications might have an impact on survival, but the presence of other congenital anomalies was not significantly associated with the mortality of omphalocele cases.

Keywords: Omphalocele, Congenital anomaly, Outcome, Mortality, Liveborn

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INTRODUCTION

Omphalocele is a congenital defect causing abdominal visceral organ herniation that remains in the peritoneal and amniotic sacs. The severity varies from minor herniation in the umbilical cord to severe defects in the form of significant protrusion that include the entire intestine and liver (1). The prevalence of omphalocele is 0.6–2.2 per 10,000 live births (2). Based on the presence of other congenital abnormalities, omphalocele can be divided into isolated omphalocele and non-isolated omphalocele. Omphaloceles are considered isolated if there are no associated anomalies, genetic abnormalities or other abnormal karyotypes that can be established.

There are reportedly several risk factors associated with pregnancy outcome with an omphalocele foetus. Omphaloceles that coexist with other structural malformations or chromosomal anomalies, commonly known as non-isolated omphaloceles, are more likely to be electively terminated and the foetus dies intrauterine (3). The reported neonatal mortality rate is 17-41%, depending on the associated anomalies (4). The most common comorbidities are pulmonary hypoplasia (70%) and congenital heart defects (71%) (5). Prenatal diagnosis has been widely performed in developed countries, making it possible to perform prenatal counselling with parents regarding the planning of labour. Delivery will be planned at the referral centre hospital, where paediatric surgeons and neonatal intensive care units are available. In our country, prenatal diagnosis has not been performed routinely. Only a small proportion of people undergo prenatal ultrasound, making the early diagnosis of congenital abnormalities, including omphalocele, often overlooked in the intrauterine period.

The two preferred methods of initial management in patients with omphalocele are surgical closure or conservative management/non-operative treatment. Early surgical repair may increase survival rates and improve the prognosis of patients with omphalocele (6).

In non-operative treatment, the technique used initially is dehydration and sac contraction, followed by repair of the residual ventral hernia. This technique is believed to minimize the risk of mortality but requires longer hospitalization and can cause secondary complications (5,7–9).

Omphalocele is also associated with a risk of mortality and morbidity in new-born. New-borns with omphalocele frequently endure prolonged hospitalizations, resulting in an increased incidence of infections and complications in their nutritional condition. Isolated omphalocele often has a better prognosis because it is not related to other organ abnormalities, although the size of the defect or the presence of surgical complications still play an important role in the outcome (10,11). If the omphalocele is an isolated lesion, the prognosis for survival after postnatal surgical correction reaches 90%. However, the presence of several other abnormalities or malformations that cannot be treated is associated with a poor overall prognosis (12). Many studies have suggested an increase in morbidity associated with the presence of multiple anomalies, genetic problems, liver position and others issues (13). This underlies the importance of antenatal diagnosis and diagnosis immediately after birth because it has the potential to contribute to increased survival.

The aim of this study was to analyse the presence of other congenital anomalies related to mortality in omphalocele patients by comparing outcomes from two different groups: an isolated omphalocele group and a non-isolated omphalocele group.

MATERIALS AND METHODS

We conducted a retrospective cohort study in the neonatal unit of Sardjito General Hospital, a tertiary hospital in Yogyakarta, Indonesia from March 2008-April 2019. The data of omphalocele cases were obtained from our birth registry. We recorded postnatal items of interest including sex, mode of delivery, gestational age at birth, birth weight, associated anomalies, management, need for surgeries, neonatal complications, and mortality from medical records. We further classified the patients into two groups and compared the parameters between them. If we found no other congenital anomalies in the postnatal assessments, we categorized patients into the isolated omphalocele group. Meanwhile, those who had other congenital anomalies besides omphalocele were categorized into the non-isolated omphalocele group.

We performed a descriptive analysis on all variables. Student's t-test was used to compare two categories, with p-values <0.05 considered statistically significant. To analyse confounding and external variables, we conducted univariate and multivariate analyses using logistic regression.

RESULTS

From March 2008 to April 2019, there were 16,789 new-born cases in our hospital. Seventy-three cases of omphalocele were identified from the registry, consisting of 29 (39.7%) male infants, 39 (53.4%) female infants and five cases (6.8%) with ambiguous genitalia. The mean birth weight and gestational age were 2,563 (±641.27) grams and 37.08 (±2.45) weeks respectively. As seen in Table I, 20 patients (27.4%) were born in our hospital, whereas 53 patients (72.6%) were referred from the district hospital. Of these, 11 (15.1%) cases were diagnosed prenatally by ultrasound and were planned to be delivered at a tertiary hospital, and 62 cases (84.9%)

Table I: Characteristics of subjects

Variable	n (%)	Mean (SD)
Sex		
Male	29 (39.7)	
Female	39 (53.4)	
Ambiguous	5 (6.8)	
Mode of delivery		
Vaginal birth	52 (71.2)	
Caesarean section	21 (28.8)	
Gestational age		37.08 (±2.45)
Very preterm (28-≤32 weeks)	2 (2.7)	
Moderate preterm (32-≤37 weeks)	18 (24.7)	
Term (37-42 weeks)	53 (72.6)	
Birth weight		2,563.12 (±641.27)
Very low birth weight (1000-1499 gram)	5 (6.8)	
Low birth weight (1500-2499 gram)	28 (38.4)	
Normal birth weight (2500-4000 grams)	39 (53.4)	
Large birth weight (>4000 grams)	1 (1.4)	
Birth place		
Inside our hospital	20 (27.4)	
Outside our hospital	53 (72.6)	
Prenatal diagnosis		
Yes	11 (15.1)	
No	62 (84.9)	
Mother's age		31.77 (±7.19)
Gestation		
Primipara	22 (30.1)	
Multipara	51 (69.9)	
Comorbidities		
Yes (Non-isolated omphalocele)	45 (61.6)	
No (isolated omphalocele)	28 (38.4)	
Management		
Surgical	13 (17.8)	
Non-surgical	60 (82.2)	
Mortality		
Yes	40 (54.8)	
No	33 (45.2)	

SD=Standard deviation

were confirmed by physical examination, as they were born and referred to our hospital after birth. We did not test for chromosomal anomalies in all cases.

The variables in the isolated omphalocele and non-isolated omphalocele groups (Table II) were then compared. Among the 73 cases, isolated omphalocele occurred in 28 (38.4%) patients and non-isolated omphalocele occurred in 45 (61.6%) patients. The mean gestational age in case of isolated omphalocele and non-isolated omphalocele was 38.14 (±2.34) weeks and 36.42 (±2.31) weeks, respectively (p=0.003). The patients in the non-isolated omphalocele group were smaller, with a mean body weight of 2,409 (±588) grams, than those in the isolated omphalocele group, with a mean body weight of 2,795 (±657) grams (p=0.013). The most commonly associated anomalies with omphalocele were heart anomalies (patent ductus arteriosus, atrial septal defect, ventricular septal defect, double outlet right ventricle) (n=19), gastrointestinal anomalies (anal atresia, oesophageal atresia, scrotal hernia) (n=10), neural tube defects (n=7), cleft lips with or without cleft palate or cleft palate (n=5), and polydactyly or syndactyly (n=1). There were also 21 cases with multiple congenital anomalies (Beckwith-Wiedemann syndrome, Patau syndrome, and Chilaiditi's syndrome). Overall, 40 infants (54.8%) died during the postnatal period, 15 patients in the isolated omphalocele group versus 25 in the non-isolated omphalocele group. Of the two groups, there were no significant differences in outcomes of mortality (p=0.87).

Table II: Clinical characteristics in isolated omphalocele and non-isolated omphalocele groups

	Isolated (n=28)	Non-isolated (n=45)	p-value
Gestational age	38.14 (±2.34)	36.42 (±2.31)	0.003
Birth weight	2,795.66 (±657)	2,409.86 (±588)	0.013
Gender			
Male	11 (37.9%)	18 (62.1%)	
Female	17 (43.6%)	22 (56.4%)	0.17
Ambiguous	0	5 (100%)	
Mother's age	31,89 (±6.84)	31,69 (±7.49)	0.91
Mother's parity			
Primipara	9 (32.1%)	13 (28.9%)	0.77
Multipara	19 (67.9%)	32 (71.1%)	
Comorbidity			
Heart anomalies	0	19 (42.2%)	0.00
Gastrointestinal anomalies	0	10 (22.2%)	0.07
Neural tube defects	0	7 (15.6%)	0.03
Cleft lip/palate	0	5 (11.1%)	0.07
Polydactyly/syndactyly	0	3 (0.07%)	0.16
Other syndrome	0	21 (46.7%)	0.00
Complication			
Sepsis	22 (78.6%)	34 (75.6%)	0.77
Pneumonia	8 (28.6%)	13 (28.9%)	0.98
Gastrointestinal perforation	7 (25%)	8 (17.8%)	0.46
Electrolyte imbalance	4 (14.3%)	10 (22.2%)	0.40
Hypoalbuminemia	7 (25%)	10 (22.2%)	0.79
Disseminated Intravascular Coagulation (DIC)	4 (14.3%)	2 (4.4%)	0.14
Hospital length of stay	19 (±16)	18 (±15)	0.81
Death	15 (53.6%)	25 (55.6%)	0.87

DIC=Disseminated intravascular coagulation

Univariate and multivariate analyses were conducted to determine a possible variable contributing to a prognostic factor of the patients with omphalocele (Table III). Based on the data, the presence of comorbidity did not serve as a prognostic factor of mortality in omphalocele patients (p=0.87). The confounding factors that might have caused death were complications such as sepsis (OR 6.78; 95% CI 0.96 to 48.13; p=0.05), pneumonia (OR 15.75; 95% CI 2.42 to 102.34; p=0.00) and gastrointestinal perforation (OR 4.71; 95% CI 0.96 to 23.14; p=0.05). Factors such as preterm birth, low birth weight, place of birth, prenatal diagnosis and mode of delivery did not contribute to the occurrence of death in infants with omphalocele.

DISCUSSION

This study reported the discharge outcome of liveborn infants with omphalocele. Our data showed that the hospital occurrence of omphalocele was 73 cases out of 16,789 new-born cases (4.3 cases out of 1,000 births). Our study showed higher results than other reports in the United States, which stated that the prevalence of birth for new-born with omphalocele was 1.92 per 10,000 livebirths. This number showed an inconsistent trend over time (14). Meanwhile, the data in Singapore in 1993-2002 claimed that the incidence of omphalocele was 2.17 per 10.000 live births (2). Since our hospital is a tertiary referral hospital for the DIY and Central Java provinces, many cases of omphalocele found in the surrounding area were referred to our hospital for further management, which consequently resulted in a high number of omphalocele cases at our hospital.

In our country, we found that the perinatal mortality of omphalocele was 54.8%. This estimation was not in line with a previous study showing that 12% of omphalocele cases resulted in neonatal death, whereas 39–41% of cases resulted in the termination of pregnancy and stillbirth (15,16). Omphalocele mortality rates were inconsistent over time. This may be due to varying gestational age, prenatal detection, perioperative care, and management of the omphalocele itself. Omphalocele and other related congenital anomalies could be detected early if routine prenatal screening has been performed. In our centre, there is no policy regarding the prenatal diagnosis of congenital anomalies, including omphalocele. Therefore, most of the patients were not identified even from the intrauterine period. Instead, they underwent the examination when they were born. Our data revealed that only 11 (15.1%) cases

Table III: Variables contributing to mortality in omphalocele patients

Characteristics	Dead (%)	Survived (%)	Univariate analysis		Multivariate analysis	
			OR (95% CI)	p-value	OR (95% CI)	p-value
Omphalocele type						
Non-isolated	25 (55.6)	20 (44.4)	1.01 (0.42-2.79)	0.87	-	-
Isolated	15 (53.6)	13 (46.4)	0.92 (0.36-2.38)			
Mode of delivery						
Vaginal birth	29 (55.8)	23 (44.2)	1.15 (0.42-3.17)	0.79	-	-
Caesarean section	11 (52.4)	10 (47.6)	0.87 (0.32-2.41)			
Gestational age						
Preterm birth	16 (84.2)	3 (15.8)	6.67 (1.73-25.59)	0.01	6.94 (0.74-64.95)	0.09
Term birth	24 (44.4)	30 (55.6)	0.15 (0.04-0.58)			
Birth weight						
Low birth weight	24 (70.6)	10 (29.4)	3.45 (1.30-9.15)	0.13	2.62 (0.49-13.95)	0.26
Normal birth weight	16 (41)	23 (59)	0.29 (0.11-0.77)		-	-
Birth place						
Outside our hospital	26 (49.1)	27 (50.9)	0.41 (0.14-1.24)			
Inside our hospital	14 (70)	6 (30)	2.42 (0.81-7.26)	0.11	2.92 (0.57-14.96)	0.19
Prenatal diagnosis						
No	33 (53.2)	29 (46.8)	0.65 (0.17-2.45)			
Yes	7 (63.6)	4 (36.4)	1.54 (0.41-5.79)	0.53	-	-
Comorbidities						
Heart anomalies	9 (47.4)	10 (52.6)	0.67 (0.23-1.91)	0.45	-	-
Gastrointestinal anomalies	8 (80)	2 (20)	3.88 (0.76-19.71)	0.10	1.48 (0.19-11.10)	0.70
Neural tube defects	3 (42.9)	4 (57.1)	0.59 (0.12-2.84)	0.51	-	-
Other syndrome	12 (57.1)	9 (42.9)	1.14 (0.41-3.18)	0.79	-	-
Complication						
Sepsis	35 (62.5)	21 (37.5)	4.00 (1.24-12.96)	0.02	6.78 (0.96-48.13)	0.05
Pneumonia	19 (90.5)	2 (9.5)	14.02 (2.95-66.66)	0.00	15.75 (2.42-102.34)	0.00
Gastrointestinal perforation	11 (73.3)	4 (26.7)	2.75 (0.78-9.65)	0.11	4.71 (0.96-23.14)	0.05
Electrolyte imbalance	8 (57.1)	6 (42.9)	1.13 (0.35-3.65)	0.84	-	-
Hypoalbuminemia	13 (76.5)	4 (23.5)	3.49 (1.01-12.03)	0.05	0.23 (0.03-2.09)	0.19
Disseminated Intravascular Coagulation (DIC)	5 (83.3)	1 (16.7)	4.57 (0.51-41.25)	0.18	4.79 (0.25-90.44)	0.29

OR=Odds ratio, CI=Confidence interval, DIC=Disseminated intravascular coagulation

were diagnosed antenatally by ultrasound. There were twenty patients (27.4%) born at our institution, while 53 patients (72.6%) were referred from a district hospital. Some of them were referred to us in the 1st week of age, which led to the delayed management of omphalocele. There were also possibilities of hypothermia, sepsis and electrolyte imbalance during the referral process, resulting in poor outcomes.

The overall survival rate in our study (45.2%) showed lower results than other studies (70-80%) (5,7). The important factors that influence the prognosis were the presence of other associated congenital anomalies. Crucial factors that alter the prognosis seemed to be the other associated anomalies. In its report, the European Surveillance of Congenital Anomalies stated that the prevalence of omphaloceles among all congenital anomalies in Europe between 2008 and 2012 was 3.13% (2.96-3.30), and 37% were related to chromosomal anomalies. In our data, 61.6% of omphalocele cases were associated with other comorbidities (non-isolated omphalocele). Kamata et al. reported that pulmonary hypoplasia was more severe in these forms, causing a higher morbidity (17,18). We found that the most common congenital anomalies associated with omphalocele were other syndromes (46.7%), such as Patau syndrome and Beckwith-Wiedemann syndrome, congenital heart defects (42.2%), gastrointestinal anomalies (22.2%), neural tube defects (15.6%), cleft palate (11.1%), and syndactyly (0.07%). We did not perform chromosomal analysis in our patients since it was costly, time consuming and had not been stated as a policy in the standard operating procedure at our centre. In the non-isolated omphalocele group, the mean of birth weight was lower than that in the isolated omphalocele group. Similarly, the mean gestational age was younger in the NIO group. This may have been caused by the problems that occurred during the intrauterine period,

so that the baby was born at a fairly young gestational age with low birth weight. Our study was similar to the other report which stated that associated malformation was the major prognostic factor of omphalocele, since it was associated with prematurity and low birth weight (19).

However, related anomalies were not recognized as prognostic factors in several reports, for example, in a study conducted by Kominiarek et al who did not find a significant difference between survival rates or complications between the two groups (isolated omphalocele and non-isolated omphalocele) (20). This finding is in line with the finding of our study, in which the presence of comorbidity did not serve as a prognostic factor of death in omphalocele patients. A contrary finding was reported by Mitanchez et al., who stated that the morbidity and mortality rates in isolated omphalocele were lower (3). Patel et al had similar results, and that there was a statement that being isolated is a better prognostic factor than the volume of the omphalocele itself (21).

In addition to congenital abnormalities associated with omphalocele, several factors are believed to affect mortality in omphalocele patients, such as the severity of omphalocele defects, any sac perforation, no surgical procedures, and complications of the surgical procedures or the omphalocele itself. Sriworarak et al stated that they reserved conservative treatment only for those whose have non-expected survival, while primary fascial closure had higher survival rate rather than staged operative procedures due to the smaller defect on the former patients (22). We had limited data with incomplete information about the size of the defect, while management (surgical vs conservative management) and comorbidities were not significant mortality predictors. Based on our data, the confounding factors that might have influenced the occurrence of death were complication related to the management of the omphalocele or to the omphalocele itself, such as sepsis, pneumonia and gastrointestinal perforation. Meanwhile, the other confounding factors such as preterm birth, low birth weight, place of birth, prenatal diagnosis and mode of delivery did not suggest a significant correlation between the incidence of death in infants with omphalocele. In another study, prematurity and low birth weight were considered as important prognostic factors, because of the presence of congenital anomalies causing preterm birth and, as a result, the baby will be born with a low birth weight (23). Suita et al concluded that prenatal diagnosis and mode of delivery had no effect on the prognosis of omphalocele. Omphalocele that is diagnosed prenatally does not always require caesarean section. Elective caesarean section is indicated only if there is a large omphalocele found prenatally that contains some parts or all of the liver (12,24).

CONCLUSION

The occurrence of omphalocele in our hospital was 4.3 in 1,000 livebirths, with an overall survival rate of 45.2%. Non-isolated omphalocele was most commonly associated with another syndrome and congenital heart disease. The presence of other congenital anomalies was not associated with the mortality of omphalocele cases. Complications, such as sepsis, pneumonia and gastrointestinal perforation, might have an impact on the survival of patients with omphalocele.

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