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A Comparative Study between Silver Impregnated Hydrofiber Dressing Verses Silver Sulfadiazine Dressing in the Non-Operative Management of Omphalocele

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Abstract **Original Research Article**

***Background*:** Omphalocele is one of the most common abdominal wall defects encountered by pediatric surgeon. Treatment options vary depending on the size of the defect, with a common option being the "paint and wait" technique, in which a topical agent is applied that allows epithelialization over the amnion sac, different approaches can be applied including silver impregnated hydrofiber dressing and silver sulfadiazine dressing in the treatment of anomphalocele. ***Objective*:** To compare the outcome of silver impregnated hydrofiber dressing and silver sulfadiazine dressing in non-operative management of omphalocele. ***Methodology*:** It was a prospective, interventional study carried out in the Department of Pediatric Surgery, Dhaka Medical College and Hospital, Dhaka, Bangladesh during the period of March 2018 to June 2020. Total 20 samples were included in this study. Among them 10 cases were neonate with omphalocele using silver impregnated hydrofiber dressing (Group A) and 10 cases were neonate with omphalocele using silver sulfadiazine dressing (Group B). Data was collected in pre-designed data collection sheet. Data was analyzed by SPSS for windows version 22. Variables were used in time to eshcharification, length of hospital stay at presentation, time to start and complete epithelialization. ***Results*:** This study shows the average age at presentation was 1.0±0.66 days in group A and 1.10±1.15 days in group B. Female (70%) predominance was found in group A, whereas male predominance (60%) were found in group B. Majority (90%) of omphalocele sac size was >5 cm in two groups. The average omphalocele sac size was 9.20±3.01 cm in group A and 7.30±2.58 cm in group B. It was observed that time to escharification was shorter in group A than group B, which was 3.30±0.82 vs 7.70±2.62days respectively. Shorter length of hospital stay at first admission was observed in group A than group B which was 5.10±1.19 vs 9.10±1.91 days respectively. It was also observed that started epithelialization was shorter in Group A (15.10±2.23 days) than Group B (18.90±3.60 days). Time to complete epithelialization was higher in group B than group A which was 103.30±16.74 vs 63.60±14.60 days respectively. Analysis revealed that shorter time to escharification, shorter length of hospital stay, shorter time to started and complete epithelialization were significant in group A than group B (P<0.05). ***Conclusion*:** It concluded that outcome of silver impregnated hydrofiber dressing is better than silver sulfadizine dressing in non- operative management of omphalacele.

Keyword: Omphalocele, Abdominal wall defects, Epithelialization, Amnion sac, Silver impregnated hydrofiber dressing, silver sulfadiazine dressing.

INTRODUCTION

Omphalocele is most frequently encountered congenital abdominal wall defect in pediatric surgery [1]. The reported prevalence of omphalocele is 0.9-3.8 per 10,000 live births in India [2]. Specifically, omphalocele is associated with Beckwith-Wiedemann syndrome, OEIS complex (Omphalocele, Exstrophy, Imperforate anus, Spinal defect) and pentalogy of Cantrell [3-5]. Most omphalocele infant may have other anomalies including cardiac, gastrointestinal, urologic, musculoskeletal and neurologic conditions [2]. The prevalence of associated anomalies is 31% to 50% of omphaloceles. These additional anomalies are various and all organs can be affected depending on the etiology. It can be neural tube defects (anencephaly, holoprosencephaly, spina bifida and rudimentary

orbits), cleft palate, single umbilical artery, amniotic fluid anomaly (oligoamnios or polyhydramnios). Omphaloceles are classified as small or giant defect and there are many anatomic classifications that determine the prognosis. The most used is Aitken classification, and the type I: larger of defects (collar base) < 4 cm, diameter of the sac <8 cm and absence of liver and type II: collar base >5 cm, diameter of sac >8 and presence of the liver in the sac [6]. Non-surgical treatment of omphalocele with primary epithelialization is considered to be a good option, although it has a higher incidence of sepsis and needs correction of the ventral hernia later in life. It was concluded that non-operative delayed treatment was associated with lower mortality compared to early stepped surgical correction and a shorter start to complete enteral feeding in the neonatal period [7]. The healing process consists of autolytic debridement of the tissue followed by viable tissue formation. Physiologically, tissue slough is a fibrous mass consisting of fibrin, deoxyribonucleic-protein, leucocytes, bacteria, proteinaceous material and serous exudate. Prolonged sloughing can result in formation of a hardened eschar formation. Silver-impregnated hydrofiber supports autolytic debridement of slough promothing healthy wound bed and eventual new tissue formation [8]. There are many topical agents used in omphalocele care [9]. Now a day's use silver sulfadiazine dressing which works by stopping the growth of bacteria that may infect an open wound. It helps to decrease the risk of the bacteria spreading to surrounding area. Silver sulfadiazine has some side effects that may lead to systemic absorption and causes hypersensitivity reactions, rashes, erythema multiforme. Incorporation of the silver ions can lead to local argyria and generalized argyria where silver accumulation may occur kidney, liver, retina [8]. Silver impregnated hydrofiber dressing also have some side effects that are cytotoxicity, staining, methaemoglobinaemia and electrolyte disturbance, longer slough separation time [10]. Silver impregnated hydrofiber dressing consists of soft non-woven sodium carboxymethylcellulose fibers which integrated with ionic silver. It is a moisture-retention dressing. It forms a gel on contact with wound fluid which incorporation of ionic silver into the hydrofibers and does not cause undue alteration in the performance properties of the base dressing. It continuously provides favorable wound moisture and exudate management. The addition of ionic silver reduces local pain, dressing changes and significant broad-spectrum antimicrobial properties with no delay in wound healing. In vitro and vivo studies have shown lower systemic silver ion concentrations. Silver impregnated hydrofiber dressing also decreased hospital stay, escherification time, epithelization time than silver sulfadiazine dressing [8]. For this reason, this study was designed to manage omphalocele by silver impregnated hydrofiber dressing and compared to silver sulfadiazine dressing in the non-operative management of omphalocele.

OBJECTIVES

General Objectives

General objective was to compare the outcome of silver impregnated hydrofiber dressing and silver sulfadiazine dressing in non-operative management of omphalocele.

Specific Objectives

- To observe the time of escherification, time of hospital stay and time of start and complete epithelialization in silver impregnated hydrofiber dressing.
- To observe the time of escherification, time of hospital stay and time of start and complete epitheliazation in silver sulfadiazine dressing.
- To compare the time of escherification, time of hospital stay and time of start and complete epithelialization between silver impregnated hydrofiber dressing and silver sulfadiazine dressing in non-operative management of omphalocele.

METHODOLOGY

It was a prospective, interventional study, conducted March 2018 to June 2020 at the Department of Pediatric Surgery, Dhaka Medical College and Hospital (DMCH), Dhaka, Bangladesh. A total of 20 sample was collected, 10 in each group.

Inclusion Criteria

- Omphalocele with physiologically stable neonate.

Exclusion Criteria

- Neonate with ruptured omphalocele sac.
- Neonate with omphalocele with unstable patient.
- Informed consent not given.

Study Procedure

Total cases were selected according to selection criteria from the patients attending at department of pediatric surgery in DMCH. After duly taking informed written consent from parent or attending guardians, total 20 samples were taken in both groups. Admission & resuscitation of the babies was done. All patients were evaluated by history, physical examination, and investigations (CBC, RBS, Serum Electrolyte, C-Reactive protein, Serum Creatinine). Neonate was kept nothing per oral and nasogastric suction initially. Parenteral nutrition was maintained by intravenous 10% glucose and electrolyte containing fluid. Intravenous broad spectrum antibiotics, inj. Phytomenadione (Vitamin k1) were given. Saline enema was given by catheter with normal saline. The patient parents were instructed about treatment procedure of silver impregnated hydrofiber dressing or silver sulfadiazine dressing and breast feeding was started depending on the condition and gradually

weaned off intravenous fluid. Neonatal intensive care unit (NICU) facilities were not provided.

Technique for Silver Impregnated Hydrofiber Dressing Application:

- The wound is cleansed with normal saline and dried with gauze.
- A silver impregnated hydrofiber dressing is applied to completely cover the defect and overlap the base of the defect by 1 cm. multiple dressings may be employed to form a single layer covering on the defect [11].
- Dressing is covered by sterile gauze and roll bandage.
- Dressing was removed by using normal saline and again similar dressing done. On 3rd day and 7th day and then 7 day's interval up to complete epithelization.

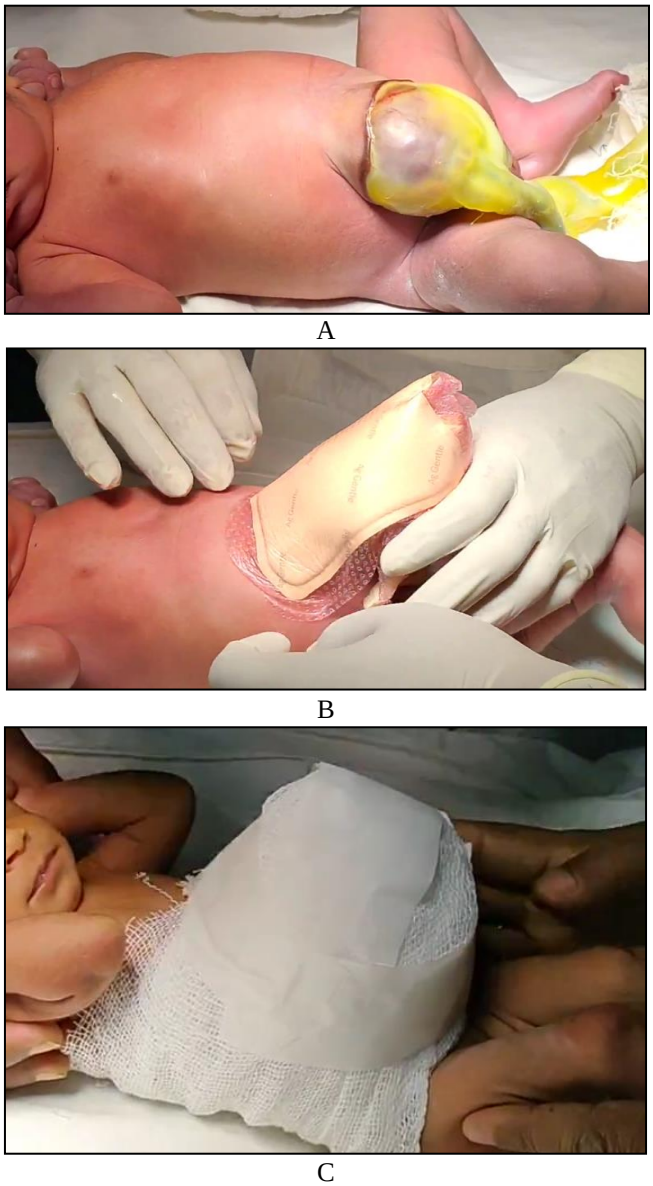

Figure I: Technique of silver impregnated hydrofiber dressing application in omphalocele: A) At 0 days of age, B) Beginning of dressing, C) Completion of dressing

Technique for Silver Sulfadiazine Cream Application:

- Approximately 20 gm of SSD cream were spread in a thin layer over the omphalocele sac using clean technique once a day [12].
- Dressing is covered by sterile gauze and roll bandage.
- Dressing was removed by using normal saline and again similar dressing done daily upto complete epithelization.

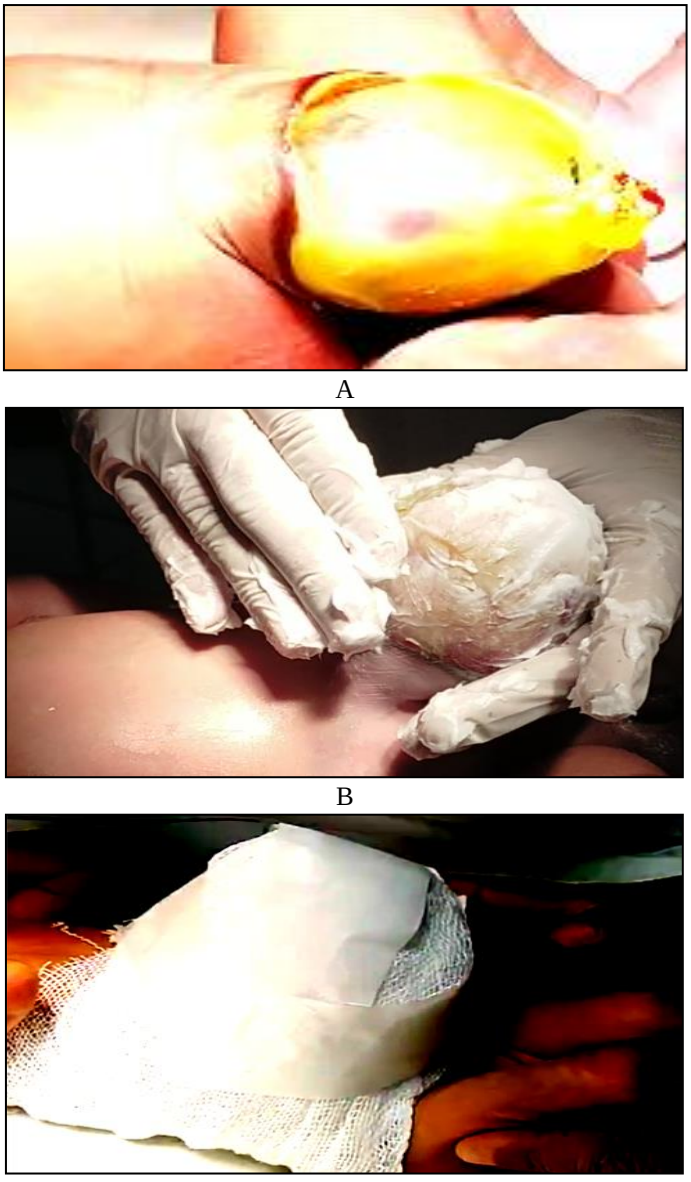

Figure II: Technique of silver salfadiazine dressing application in omphalocele: A) At 0 days of age, B) Beginning of dressing, C) Completion of dressing

Data Analysis

After collection of data, all data was compiled in a master table first. Data were analyzed by SPSS version 22.0. Qualitative variables of this study were expressed as percentage and proportion. Quantitative variables were expressed as mean, standard deviation. Statistical analysis was done by using appropriate statistical tool like 'chi-square' test, students t' test where applicable. The results were presented in tables and figures etc. A "p" value <0.05 was considered as significant.

Ethical Considerations

Prior to commencement of the study ethical clearance was taken from the Ethical Review Committee of DMCH. Informed written consent from parents or legal guardian was taken after description of the disease process, conditions of the baby and treatment options (i) application of silver impregnated hydrofiber dressing (ii) application of silver sulphadizine dressing.

RESULTS

In this study total 20 samples were included. Among them 10 cases were neonate with omphalocele using silver impregnated hydrofiber dressing (Group A) and 10 cases were neonate with omphalocele using silver sulfadiazine dressing (Group B). This result acknowledged the outcome of silver impregnated hydrofiber dressing and silver sulfadiazine dressing in infant with omphalocele. This result is described below with tables and figures:

Table 1: Distribution of age at presentation of the study participants (N=20)

Age at presentation (in day)	Group A (n=10)	Group B (n=10)	P value
	No (%)	No (%)	
0 days.	2(20%)	3(30%)	0.362
1 days.	6(60%)	6(60%)	
2 days.	2(20%)	0(00%)	
4 days.	0(00%)	1(10%)	
Mean ±SD	1.0±0.66	1.0±1.15	

Table 1 showed, 20% children were age 0 day, 60% were 1 day and 20% were 2 days in group A. On the other hand, 30% children were age 0 day, 60% were 1 day and 10% were 4 days in group B. The difference was statistically not significant between two groups (P=0.362).

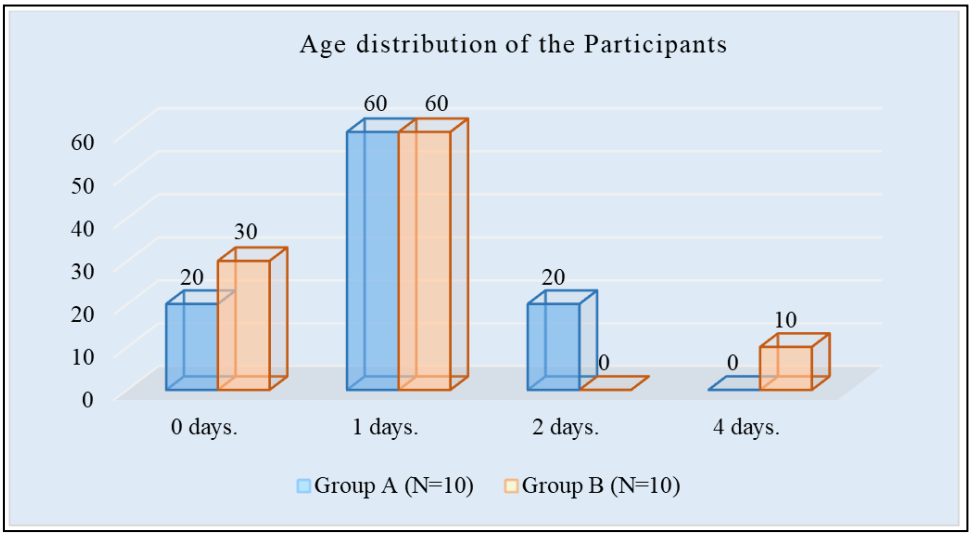

Figure III: Bar chart showed age wise participants distribution (N=20)

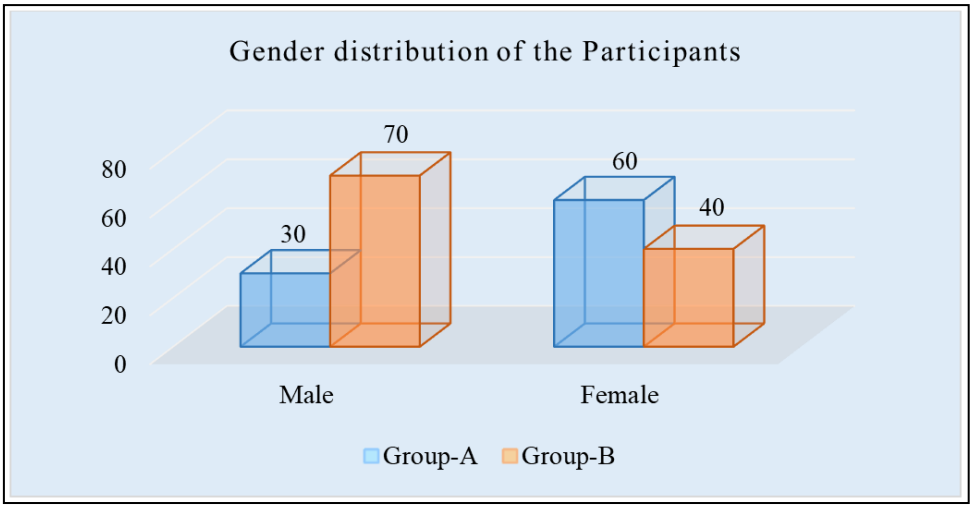

Figure IV: Bar chart showed gender wise participants distribution (N=20)

Figure IV showed 30% were male and 70% were female in group A. On the other hand, 60% were male and 40% were female in group B. The difference was statistically not significant between two groups (P=0.068).

Table 2: Birth history of the study participants (N=20)

Birth history	Group A(n=10)	Group B(n=10)	P value
	No (%)	No (%)	
Antenatal care			
None	1(10%)	2(20%)	0.531

Visit	9(90%)	8(80%)	
Delivery			
Premature	1(10%)	1(10%)	0.100
Full term	9(90%)	9(90%)	
Birth weight			
≤2.5 kg	5(50%)	5(50%)	0.576
>2.5 kg	5(50%)	5(50%)	
Mean ±SD	2.51±0.88	2.70±057	

Table 2 showed majority visit antenatal care (90% in group A and 80% in group B). Majority (90%) were full term babies between two groups. Half of the baby's birth weight ≤2.5 kg and >2.5 kg between two group. All are delivered by caesarean section between two groups. Analysis was observed that no significant different between two groups in birth history (P>0.04).

Table 3: Omphalocele (sac) size of the study participants (N=20)

Omphalocele (sac) size	Group A(n=10)	Group B(n=10)	P value
	No (%)	No (%)	
≤5 cm	1(10%)	1(10%)	0.147
>5 cm	9(90%)	9(90%)	
Mean ±SD	9.20±3.01	7.30±2.58	

Table 3 showed majority of the omphalocele sac size was >5 cm in two groups which was 90% each group. The average omphalocele size 9.20±3.01 cm in group A and 7.30±2.58 cm in group B. The difference was statistically not significant between two groups (P=0.147).

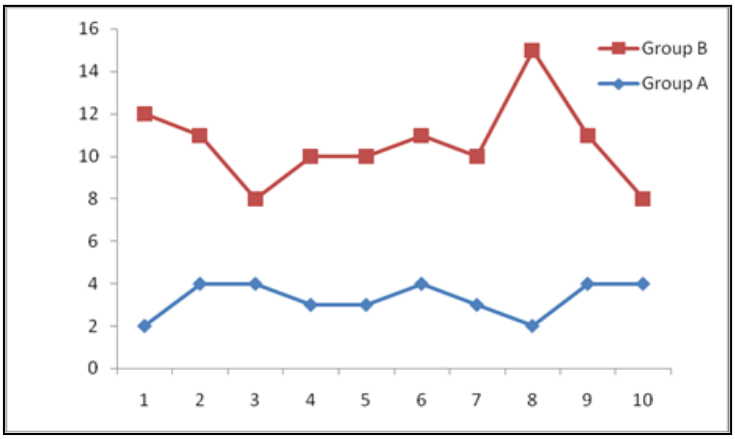

Figure V: Line chart showed time to escharification between study group (N=20)
Group A: Neonate with omphalocele using SIHD.
Group B: Neonate with omphalocele using SSD.

Figure V showed, time to escharification was 3.30±0.82 in group A and 7.70±2.62 in group B. It was observed that time to escharification was higher in group B than group A.

Figure VI: Escharification after using silver impregnanted hydrofiber dressing (4 days)

Figure VII: Escharification after using silver sulfadiazine dressing (7 days)

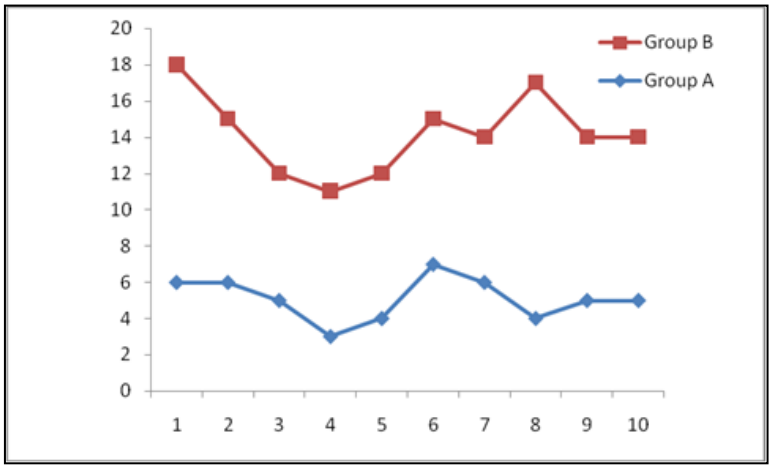

Figure VIII: Line chart showed Duration of hospital stay at first admission between two groups (N=20)
Group A: Neonate with omphalocele using SIHD.
Group B: Neonate with omphalocele using SSD.

Figure VIII showed, at first admission hospital stay was 5.10±1.19 in group A and 9.10±1.91 in group B. It observed that at first admission hospital stay were higher in group B than group A.

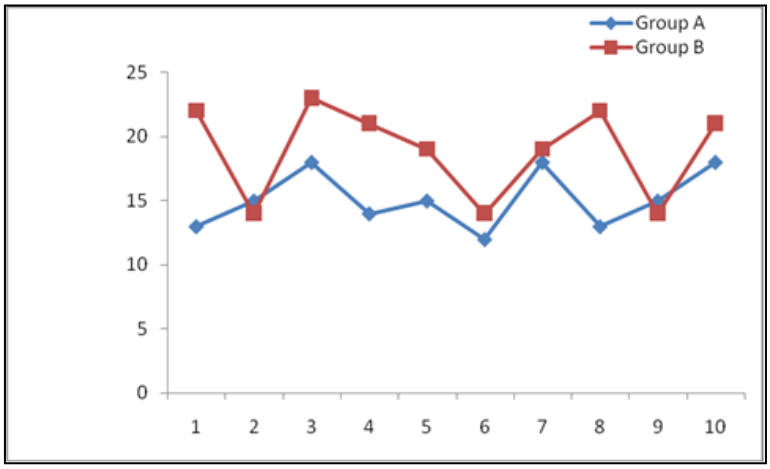

Figure IX: Line chart showed Time to started epithelization between two groups (N=20)
Group A: Neonate with omphalocele using SIHD.
Group B: Neonate with omphalocele using SSD.

Figure IX showed Time to started epithelization was 15.10±2.23 higher in group A and 18.90±3.60 in group B. It was observed that in time to started epithelization was higher in group B than group A.

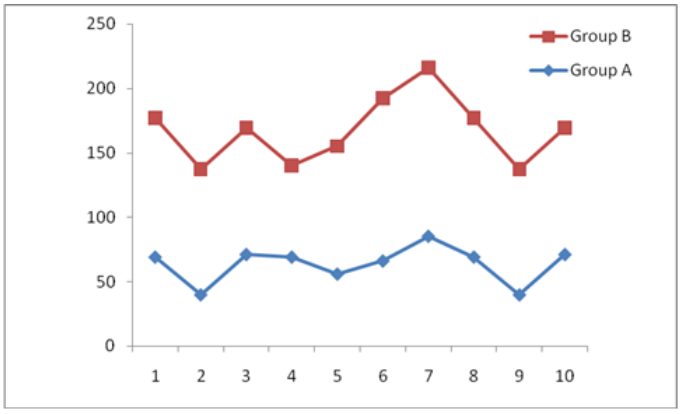

Figure X: Line chart showed Completed time to epithelization between two groups (N=20)
Group A: Neonate with omphalocele using SIHD.
Group B: Neonate with omphalocele using SSD.

Figure X showed, time to completed epithelization was 63.60±14.60 in group A and 103.30±16.74 in group B. It was observed that in time to started epithelization was higher in group B than group A.

Figure XI: Complete epithelization by silver impregnated hydrofiber dressing

Figure XII: Complete Epithelization by silver sulfadiazine dressing

DISCUSSION

The present study findings were discussed and compared with previously published relevant studies. Regarding time to escharification, length of hospital stay, time to started and complete epithelization. This study shows 20% were male and 80% were female in group A. On the other hand, 60% were male and 40% were female in group B. Therefore, the findings of the study are in well agreement with the findings of the other research works [12]. Mac-Bird *et al.,* (2009) [13] they reported that omphaloceles occur more frequently in males than in females. In this study average birth weight was 2.51±0.88 kg in group A and 2.70±0.57 kg in group B. Therefore, the findings of the study are in well agreement with the findings of the others [14] they found average birth weight 2.84 kg. In this study shows majority of omphalocele size (sac) was >5 cm in both groups which was 90% in each group. The average diameter omphalocele (sac) size was 9.20±3.01 cm in group A and 7.30±2.58 cm in group B. The difference was statistically not significant between two groups (P=0.147). Therefore, the findings of the study are in well agreement with the findings of the other research works [12] they found omphalocele as a defect larger than 10 cm in diameter. A narrow neck of the sac (<5 cm) in 3 babies. Depending on the size of defect (< or >5 cm) and content of sac, it may be classified as omphalocele minor or major, respectively [15]. In this study shows time to escharification was shorter in group A than group B which was 3.3±0.82 days' vs 7.70±2.62 days respectively. Therefore, the findings of the study are in well agreement with the findings of the other research works (Marical *et al.,* 2015 and Kogut and Fiore, 2018) [8, 14]. Marical *et al.,* (2015) [8] found time to escharification was 3.1±0.79 days in silver impregnated hydrofiber dressing and 7.72±2.59 days in silver sulfadiazine dressing group. Another study Kogut and Fiore (2018) [14] found Kogut and Fiore, 2018 found time to escharification was 3.21±0.83 days in silver impregnated hydrofiber dressing and 7.69±2.36 days in silver sulfadiazine dressing group. Previous study (Almond *et al.,* 2010) [4] reported shorter time to escharifiation in silver impregnated hydrofiber dressing than silver sulfadiazine dressing group. All studies found shorter escharification time in silver impregnated hydrofiber dressing and then in silver sulfadiazine dressing group. This study shows shorter hospital stay was in group A than group B which was 5.10±1.19 days' vs 9.10±1.91 days respectively. Analysis observed that shorter time to hospital stay at first admission in group A than group B which was statistically significant (P<0.05). Similar study Marical *et al.,* (2015) [8] found time to hospital stay was 5.45±1.32 days in silver impregnated hydrofiber dressing and 9.64±2.12 days in silver sulfadiazine dressing group. Another similar type of study Kogut and Fiore (2018) [14] found time to hospital stay was 5.34±1.26 days in silver impregnated hydrofiber dressing and 9.37±2.38 days in silver sulfadiazine dressing group. Previous study (Almond *et al.,* 2010) [4] reported shorter hospital stay in silver impregnated hydrofiber dressing than silver sulfadiazine dressing group. All studies found shorter time to hospital stay in silver impregnated hydrofiber dressing and then in silver sulfadiazine dressing group. In this study it was observed that time to start epithelialization was shorter in group A than group B which was 15.10±2.23 days' vs 18.90±3.60 days respectively. Analysis observed that time to start epithelialization were in group A than group B which was statistically significant (P<0.05). These findings consistent with other research works (Marical *et al.,* 2015 and Kogut and Fiore, 2018) [8, 14]. Marical *et al.,* (2015) [8] found time to start epithelialization was 15.45±3.29 days in silver impregnated hydrofiber dressing and 19.14±3.54 days in silver sulfadiazine dressing group. Another similar type of study Kogut and Fiore (2018) [14] found time to hospital stay was 15.21±2.26 days in silver impregnated hydrofiber dressing and 19.13±3.41 days in silver sulfadiazine dressing group. Regarding time to complete epithelialization was higher in group B than group A which was 103.30±16.74 day's vs 63.60±14.60 days respectively. Analysis observed that shorter time to completed epithelialization were in group A than group B which was statistically significant (P<0.05). These findings consistent with other research works [8, 14]. Marical *et al.,* (2015) [8] found time to complete epithelialization was 64.39±17.39 days in silver impregnated hydrofiber dressing and 105.40±23.29 days in silver sulfadiazine dressing group. All studies found shorter time to complete epithelialization in silver impregnated hydrofiber dressing and then in silver sulfadiazine dressing group. In this study sample size was small; study period was short and carried out in a single center. Further research must also take place to develop specific evidenced-based guidelines for the treatment of neonate with omphalocele to deliver safe and effective patients care.

CONCLUSIONS

So it is concluded that outcome of silver impregnantedhydrofiber dressing is better than silver sulfadizine dressing in non-operative management of omphalacele.

LIMITATIONS

- Neonatal echocardiogram facilities were not available in our center.
- Counseling of parents about dressing was difficult.
- Neonatal intensive care unit (NICU) facilitates was not available.
- Regular dressing and timely follow up schedule maintaining was difficult.

RECOMMENDATION

Our recommendation is that outcome of silver impregnated hydrofiber dressing is better than silver sulfadiazine dressing in non-operative management of

omphalocele. Further long term broad based multicenteric study with a large sample is needed for validation of the findings.

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