Comparison of Endoscopic Balloon Dilation with Bougie Dilation in Children with Esophageal Atresia

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Abstract

Introduction: Esophageal stenosis is a complication that can occur following surgical treatment of esophageal atresia. Esophageal stenosis should be treated with some methods. One of these methods is using dilation and there are different devices for dilation. In this study we have

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compared the outcomes of the endoscopic esophageal dilation by balloon or bougie.

material and methods: This is a cross-sectional study that has been performed on 40 children in two groups including the bougie group and the balloon group with equal members. Dilation by balloon or bougie was performed and data of these procedures were collected and analyzed.

Result: There were 20 patients in each group and the mean age of children was 21/33±12/46 months. All symptoms of stenosis were resolved by performing the bougie or the balloon dilation and these procedures were significantly effective. There was no difference between the balloon dilation or bougie dilation.

Conclusion: There is no difference between balloon and bougie dilation. Both of them can be used effectively for esophageal stenosis.

Keywords

- Bougie dilation
- Balloon dilation
- esophageal atresia
- esophageal stenosis
- pediatric

Introduction

Esophageal atresia is a congenital anomaly with the annual incidence of one in every 2,500 live births.[1-2] In this anomaly, the connection between the esophagus and the patient's stomach is lost, which can be with or without a fistula between the esophagus and the trachea.[3] Frequent drooling and nasal discharge with cough, cyanosis, and respiratory distress are commonly reported in infants with esophageal atresia.[4] Esophageal atresia has equal incidence in both genders.[5] Failure to pass an orogastric tube is a common finding in esophageal atresia. On chest X-ray, the tube will stop short of the stomach and the coiled tube will often be visible above the level of esophageal atresia. A little volume of water-soluble contrast material can be injected into the orogastric tube under fluoroscopic guidance to make a definite diagnosis.[6] The primary treatment for esophageal atresia is the reconstruction of the esophagus by surgery. Due to the improvement of surgical methods and pre- and postoperative care, the survival rate in these patients has increased up to 95%.

Studies have shown a reduction in mortality and morbidity in patients with esophageal atresia and an increase in their quality of life after surgery. However, surgery may cause complications such as stenosis or leakage at the anastomotic site, recurrent fistula, gastroesophageal reflux disease, or esophageal dysmotility.[7-12] Anastomotic stenosis is the main complication after reconstructive esophageal surgery.[13-14] Balloon dilation and bougie dilation are two of the methods for treatment of this complication.[15-18] This study aimed to compare the balloon dilation and bougie dilation for the treatment of esophageal stenosis after esophageal surgery in children with esophageal atresia.

materials and methods

This study received ethical code from the ethical committee of Shahid Beheshti university of medical sciences (IR.SBMU.MSP.REC1398.523). This cross-sectional study was conducted since January till December of 2016. Pediatric patients with esophageal atresia who developed esophageal stricture after reconstructive surgery were referred to the specialized clinic of Mofid Children's Hospital for dilation and were enrolled in the study. After receiving written consent from the parents (mother and father), the patients underwent endoscopic dilation. Inclusion criteria were diagnosis of esophageal atresia in the patient based on clinical examination, clinical manifestation, radiography of the upper gastrointestinal tract, endoscopy of the patient, and history of reconstructive esophageal surgery. Exclusion criteria were refusal of participating in the study, patients with no follow-ups, patients without confirmed stenosis or stricture, history of gastric pull-up or colon interposition surgery in the patient.

The esophageal strictures were proven by radiology and/or endoscopy. Techniques of dilatation by the balloon or bougie were used to treat esophageal stricture in the studied participants. The research data were collected through a researcher-made questionnaire. An anesthesiologist administered general anesthesia by midazolam, ketamine, fentanyl, propofol, lidocaine and sevoflurane inhaled gas. We utilized balloons (Boston Scientific, Natick, MA, USA) that were blown for 2 minutes in every dilation and increased by a maximum pressure of 1 atmosphere. The balloon sizes were 14 to18 Fr. with 1 to 3 atmosphere pressure.

Before performing bougie dilation, the lubricant gel is applied to the bougie and the bougie is passed through the mouth and cricopharyngeal area under general anesthesia with the same agents as mentioned above. During fluoroscopy, bougie via catheter dilators is utilized. The Savary–Gilliard is the used bougie. We use bougie dilation from small size to large size based on the size of stricture. The size of the bougie is different for everyone and is related to the size of stricture and age of patients. If it passes the stricture, dilation continues until the largest size of bougie. The optimal number of dilations per session remains unknown because it is related to the size of structure and age of the child. The size of the bougie to be used initially should be approximately the diameter of the structure or slightly larger. We performed up to three or four dilations in each session. The endpoint of dilation was the resolution of dysphagia symptoms. Patients were divided into two groups (bougie versus balloon) with equal population and data were recorded and were collected into SPSS 20 software for statistical analysis.

Mean and standard deviation were used to describe quantitative variables, and frequency and frequency percentage were used to describe qualitative variables. Fisher's exact test and Chi-square were used to investigate the relationships between variables. In all calculations, a level of less than 0.05 is considered significant.

Result

In this study, 40 pediatrics were evaluated. The mean age of the participating patients was 21/33±12/46 months with a range of 7 to 132 months. Thirty-two neonates (79.5%) were term and 8 (20.5%) were pre-term. The mean fetal age of preterm pediatrics was 34±2 weeks with a range of 30 to 37 weeks. Patients were divided into two groups including balloon group and bougie group, equally. In the balloon group there were 13 (65%) term patients and 7 (35%) preterm patients. One preterm infant was in the bougie group (5%) and other 95% were term patients. The mean birth weight of pediatrics was 2810 ± 598.5 grams. Also, at the time of procedure, average weight of these patients was 13.13±5.91 kg. The mean height of participants at birth was 84.93±8.2 cm and the current mean height of these pediatrics was 88.25±22.94 cm. The average head circumference of newborns at birth was 33.53±1.41 and was 49.94±3.97 cm at the

time of procedure. Also, the average MUAC was equal to 140.55±15.96 cm. In these 40 patients, (30%) 12 babies were the result of consanguineous marriage and (70%) 28 babies were the result of unrelated marriages. Based on BMI and weight for height, in the balloon group there were 12(60%) normal cases, 7(35%) cases of moderate wasting and (5%) 1 case of severe wasting. In the bougie group (55%) there were 11 normal cases, 7(35%) cases with moderate wasting and 2(10%) cases with severe wasting, with no statistical significance (P = 0.83). Among 20 patients in the balloon group, 2(10%) patients had cardiac anomalies, 1(5%) child had anorectal anomaly, and 3 (15%) cases had limb anomalies. In the bougie group, 3 (15%) patients had cardiac anomalies and 2 (10%) patients had anorectal anomaly and 1 (5%) infant had a limb anomaly.

In terms of clinical manifestations before procedures in the balloon group it was observed that 4 (20%) patients had a choking episode, and 3 (15%) had cyanosis. In the bougie group, 2 (10%) patients had choking spells, and 1(5%) patients had cyanosis. All of these manifestations were removed after the procedures. These changes between the two groups were not statistically significant (P = 0.23). In the balloon group, there were 4 (20%) patients with tracheoesophageal fistula (TEF). In contrast, in the bougie group, there were 2 (10%) patients with TEF. In the balloon group, one (5%), 4 (20%) and 1 (5%) patients had tracheomalacia, laryngomalacia, and bronchomalacia respectively. Also, these findings are equal to 0, 1 (5%), and 0 in the bougie group, respectively. None of those had statistically significant values (P- value for all> 0.05).

In **Table 1**, we can see clinical symptoms after balloon dilation or bougie dilation. Six (30%) neonates in the balloon group and 2 (10%) neonates in the bougie group had postoperative regurgitation. Of these 6 neonates in the balloon group, 3 (50%) after the first dilation had regurgitation, and 50% were treated. Regurgitation were resolved in 2 and finally in one of them after second and third balloon dilation, respectively, which is statistically significant (P = 0.01). In the bougie group, two neonates had regurgitation after the first bougie dilation. These two neonates were treated but this difference was not statistically significant (P-value= 0.08).

Table 1: Clinical symptoms post operation and after balloon dilation or bougie dilation

	Regurgitation	Dysphagia	Vomiting	Food-Impaction	gas bloating
	Balloon				
post-surgery	6(30%)	6(30%)	14(70%)	9(45%)	0
after first dilation	3	5	12	9	1
after second dilation	1	5	2	9	0
after third dilation	0	0	1	4	0
after fourth dilation	0	0	1	3	0
after fifth dilation	0	0	1	0	0
P-value during time balloon	0.01	0.01	<0.001	0.08	0.40
	Bougie				
post-surgery	2	11	20	10	3
after first dilation	0	8	13	13	2
after second dilation	0	6	5	11	0
after third dilation	0	0	2	3	0
after fourth dilation	0	0	1	2	0
P-value during time bougie	0.08	<0.001	<0.001	<0.001	0.08
P-value between groups	0.55	0.86	0.90	0.91	0.27

In comparison between the two groups, no significant difference was observed in terms of the effect of each procedure on the improvement of regurgitation (P = 0.55). Six patients (30%) in the balloon group had postoperative dysphagia, which decreased to 5 cases after the first balloon dilatation, and this number did not change after the second balloon dilation but reached zero after the third balloon dilation (P = 0.01). This was statistically significant. In the bougie group 11 (55%) neonates had

postoperative dysphagia, which after the first procedure, it reached to 8 cases and after the second dilation reached 6 cases. After the third time, all cases were treated and it was statistically significant (P = 0.001). In terms of the effect on the improvement of dysphagia, with P-value of 0.86, no statistically significant difference was observed. About vomiting after surgery in both groups, 14 (70%) patients from the balloon group had vomiting after surgery, which after the first balloon dilation this number reached to 12 cases, after the second procedure it reached to two cases, after the third balloon dilation it reached to one case, and after the fourth and fifth attempts, vomiting was resolved in all patients that was statistically significant (P = 0.001). Twenty (100%) patients in the bougie group had postoperative vomiting. After the first bougie dilation, 13 cases had vomiting, after the second procedure, 5 cases and after the third intervention it reached to two cases. Finally, after the fourth dilation it reached to one case which is significant (P <0.001) and in comparison, between the effect of balloon and bougie on the treatment of vomiting, there was no statistically significant difference between the two groups (P-value =0.9).

In terms of food impaction after surgery, there were 9 (45%) patients in the balloon group who had postoperative food impaction, which did not change after the first and second rounds of balloon dilation, and after the third time, it reached to 4 cases. After the fourth time of balloon dilation, 3 cases remained with food impaction. After fifth time, food impaction was resolved in all cases and there was no statistically significant difference about the balloon dilation effect (P = 0.08). Ten (50%) patients in the bougie group had food impaction after surgery, which increased to 13 cases after the first round and after the second turn has reached to 11 cases. After the third time it reached to 3 cases and after the fourth time it reached to two cases which was statistically significant (P-value <0.001). Comparing the effect of balloon and bougie dilation on improving food impact, statistical difference was not observed. In the following, we will examine the incidence of bloating after performing balloon and bougie dilation separately in the groups. As shown in the table 1, there were no patients in the balloon group who had bloating after surgery. There was 1 (5.3%) patient who had bloating after the first balloon dilation but it was resolved after the second attempt

(P = 0.4). In the bougie group, there were 3 (60%) patients who had bloating after the operation. There were 2 patients who still had bloating after the first bougie dilation and this complication was resolved after second time of dilation (P = 0.08). This difference was not statistically significant. In comparison between the two groups of balloon and bougie in regard to the improvement of bloat symptom, there was no significant difference (P = 0.27).

In **Table 2**, we evaluated the esophageal endoscopy results after the balloon dilation. Of the 20 cases of stenosis that required balloon dilation, (70%) 14 required a second balloon dilation, 6 (30%) required a third balloon dilation, 3 (15%) required a fourth balloon dilation, and 1 (5%) required a fifth balloon dilation, which was statistically significant (P <0.001). Erythema was reported in two cases in the fourth round of the balloon dilation, which was not mentioned in the fifth round and this difference was not statistically significant (P = 0.49). In one case, the ulcer was mentioned in the second time of endoscopy, which disappeared in the next time and it was not statistically significant (P <0.999).

Table2: Endoscopic results after balloon dilation

	E1	E2	E3	E4	E5	p-value
Stenosis	20 N=20 R=0	14 N=0 R=14	6 N=0 R=6	3 N=0 R=6	1 N=0 R=1	<0.001
Ulcer	0 N=0 R=0	1 N=1 R=0	0 N=0 R=0	0 N=0 R=0	0 N=0 R=0	>0.999
Erythema	0 N=0 R=0	0 N=0 R=0	0 N=0 R=0	2 N=2 R=0	0 N=0 R=0	0.49

N = New items added
R = items that already exist

Table 3 describes the results of the bougie dilation. Of the 20 patients who underwent the first bougie dilation, 7 had stenosis. Out of 14 patients who underwent the second bougie dilation, 5 cases had stenosis. Of the three cases that underwent dilation for the third time, two cases of stenosis were reported. Of the two cases that underwent bougie for the fourth time, one case of stenosis was reported. There was no significant difference in the incidence of stenosis in the bougie group. Also, there was no statistically significant difference between two groups.

Table 3: endoscopic results after bougie dilation

	Stenosis	GER	NL	patients with esophageal disorder	تعداد کلی
	Balloon				
first	7	0	0	13	20
second	5	2	0	9	14
third	3	0	0	3	6
fourth	1	1	0	2	3
fifth	1	0	0	1	2
P-value during time balloon	0.96	>0.999			
	Bougie				
first	6	0	0	14	20
second	4	0	0	9	13
third	2	0	0	1	3
fourth	1	0	0	1	2
P-value during time bougie	0.73				
P-value between groups	0.93	>0.999			

In Tables 4 and Tables 5, we evaluated the relationship between the frequency of dilation and the techniques and the intervals between the sessions in patients in both the balloon and the bougie groups, respectively. There were no significant differences in these terms between the two groups.

Table4: Relationship between dilatation frequency and dilation technique in patients

type of dilation	mean±SD	median (minimum-maximum)	P-value
balloon	2/1±2/15	2 (5-1)	0/36
bougie	1/0±9/91	2 (4-1)	
total	2/1±05/03	2 (5-1)	

Table5: Relationship between intervals of dilation sessions with dilation technique in patients

		mean	S. D	median	minimum	maximum	P-value
age in the first time (month)	balloon	8/85	5/50	7/5	2	24	0/36
	bougie	10/40	5/10	10	4	24	
	total	9/62	5/29	9/5	2	24	-
interval between first	balloon	18/71	13/68	14/50	5	48	0/61
	bougie	16/53	7	18	6	27	

and second session (month)	total	17/66	10/84	15	5	48	-
interval between second and third session (month)	balloon	15/50	8/57	15	6	30	0/81
	bougie	14	9/16	12	6	24	
	total	15	8/21	12	6	30	-
interval between third and fourth session (month)	balloon	18	10/39	24	6	24	0/49
	bougie	12	0	12	12	12	
	total	15/60	8/04	12	6	30	

Discussion

In this study that was performed on 40 patients with esophageal atresia, bougie dilation or balloon dilation was performed. The mean age was 21/33±12/46 months. Among patients 79.5% neonates were term. The patients were divided into two groups including bougie and balloon groups and each contained 20 patients. In a study by Michuad et al it was observed that the mean age of patients with esophageal atresia was 24 months and that was similar to our study (19). In the Michuad et al study it was found that the most common clinical manifestation of congenital esophageal stenosis is nothing. In fact, more than 30% of patients with congenital esophageal stenosis have no symptoms and its diagnosis is incidentally. Other common clinical manifestations are dysphasia, vomiting, food impaction, and respiratory symptoms, respectively. In the current study it was observed that the most prevalent clinical symptom was vomiting at the time of diagnosis in both groups, and food impaction and dysphagia were in second and third places, respectively. These results were different from that of the findings of Michuad et al. These

differences may come from differences in genetics because the present study was performed in iranian patients but Michuad et al study was performed in France. In the Michuad et al study it was observed that 56% of patients were treated with first balloon dilation and balloon dilation was complicated in 3.4% of patients. In the current study, we observed about 65% of patients were treated after first balloon dilation and this percentage of success is near to Michuad et al study. There was no complication after the balloon dilation in the current study.[19]

In the study by Lang et al it was observed that, 34 symptomatic patients were divided into 3 groups and bougie dilation were performed for them as following: group-C, 178 dilation with bougie, group B, 202 dilation with bougie and group A, 16 patients who had 52 balloon dilations. The dilation was carried out under intravenous sedation using a combination of midazolam and etomidate. They concluded that the dilation was effective in all patients and involved minimal trauma. The strictures required 1 to 7 procedures (median 2) for a good treatment result. The observed complications were perforation, pneumothorax and compression of the trachea. They concluded that balloon dilation is more effective than bougie dilation. Complications in balloon dilation were not very common.[20] In the current study, we performed fewer dilations than Lang et al study in both groups. Also, we used Midazolam, ketamine, fentanyl propofol, lidocaine, Sevoflurane inhaled gas for sedation. We found that bougie and balloon are similar in the term of effectiveness in the treatment of esophageal stricture and it was different from Lang et al study. In the current study strictures needed 5 times of dilation and it is approximately similar to Lang et al study.[20]

Jayakrishnan & Wilkinson showed that fluoroscopically guided balloon dilatation was safer and had less technical problems than the dilation with the bougie and would be used as the first choice of therapy for patients with esophageal stenosis. In the current study we observed that there was no statistical significant difference between the two methods.[21]

In Gurfinkel et al study that was performed on 24 patients with esophageal stricture, they compared balloon and bougie dilation effectiveness in these patients. They found that there were 4.5 dilations on average (range 1-22). At the time of diagnosis, the average age was 3.9 ± 5.7 years. The

median treatment time was 5.5 months, with a 2.25-year follow-up following the final dilation. In 11 patients, dilations were regarded as failures (26.2 percent). Causes of stenosis were caustic injury, achalasia, and others. Complication rate was about 3%. They concluded that the lower complication rate and success in the esophageal stricture treatment is less related to method of treatment (bougie or balloon) and more related to causes of stenosis. In the present study we observed that bougie or balloon dilation was performed 5 or six times for patients. The mean age was 21/33±12/46 and our patients had lower age than that of the Gurfinkel et al study. There was no complication in the present study. In the current study we observed that the method of dilation had no difference in the results of treatment and type of esophageal disorder is an important that affect the result of dilation. These findings were similar to Gurfinkel et al study's conclusion.[22] Davidson et la stated that there was one perforation after the procedure, which was managed conservatively (complication rate = 0.4%).[23] In the study by Podar et al, six esophageal perforations occurred during 648 dilation sessions (0.9%).[24] It seems that expertness in doing procedures is an important factor that affects the outcomes of dilation because in some studies complications occurred and in some studies like our study, no complication occurred. Also, rates of complications varied.

Scolapio et al concluded there were no significant differences between the bougie dilation and balloon dilation with regard to immediate relief of dysphagia or the need for repeat dilatation at one year. This study has similar findings to the current study because we observed that these two methods for dilation had no differences.[25]

In a study by Alshamiri et al the number of dilations ranged from 1 to 8 and it was approximately similar to our study.[26]

In the study by Antonio et al, a total of 165 balloon dilations were undertaken, with an average of 279 per patient (range 1-9). Age range at diagnosis was 1 to 36 months (mean 10.5). The treatment was effective in 47 patients (79.7%) and ineffective in 12 (20.3%). The median follow-up period was 19.5 months. No perforation occurred. As we said above, it seems that the results of dilations are related to the underlying disorder and expertness of the operator, the method of dilation and all factors related to the procedure.[27]

Conclusion

The two methods of balloon dilation and bougie dilation are equally effective in treating patients with esophageal stenosis, without any statistically significant difference in the number of dilations required for each patient, time intervals between dilations, clinical symptoms, reduction of airway abnormalities and respiratory complications. Based on the results of the present study, it can be said that although esophageal dilation in pediatrics with balloon and bougie have same results but, balloons are disposable, so the cost of dilation with bougie is lower than balloons and bougie dilation is a cost-effective way for dilation.

Ethical Considerations

This study received ethical code from the ethical committee of Shahid Beheshti university of medical sciences (IR.SBMU.MSP.REC1398.523).

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Conflict of interests

There are no conflicts of interest.

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