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BÙI DUY DŨNG

EVALUATION OF ACHALASIA TREATMENT RESULTS BY ENDOSCOPIC AIR BALLOON DILATATION

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DANH MỤC CÁC CÔNG TRÌNH NGHIÊN CỨU KHOA HỌC ĐÃ CÔNG BỐ LIÊN QUAN ĐẾN LUẬN ÁN

1. Bui Duy Dung, Nguyen Lam Tung, Tran Viet Tu (2022). Clinical and subclinical characteristics of achalasia patients at Bach Mai Hospital and 108 Military Central Hospital. *Journal Of 108 - Clinical Medicine And Pharmacy* Vol.17 - No2: pp 8-13.
2. Bui Duy Dung, Nguyen Lam Tung, Tran Viet Tu (2022). Treatment efficiency of achalasia with esophageal balloon dilation at Bach Mai Hospital and 108 Military Central Hospital *Journal Of 108 - Clinical Medicine And Pharmacy*. Vol.17 - No2: pp 30-36.

THESIS TOPIC

Esophageal achalasia (Achalasia) is a primary esophageal motility disorder characterized by loss of esophageal motility and impaired response to relaxation of the lower esophageal sphincter (which is already hypertonic) for the Mayberry swallow. These abnormalities cause functional obstruction at the gastroesophageal junction.

Achalasia is the most common and important disease in esophageal motility disorders, although it is a rare disease with an incidence of about 1.6/100,000 people per year and a prevalence of about 10.8/100,000 people. Common symptoms include choking on both solids and liquids, reflux, dyspnea, chest pain, and weight loss .Although it is a benign disease, achalasia can severely affect the normal life and activities of patients due to choking, causing prolonged meals. Esophageal dysphagia can lead to sleep reflux, chest pain, esophagitis, or, worse, aspiration pneumonia or acute respiratory failure.

Because the disease has a low incidence and early symptoms are similar to gastroesophageal reflux disease, it is often diagnosed late or mistaken for gastroesophageal reflux disease. When a patient is suspected of achalasia, necessary investigations such as gastroesophageal endoscopy should be carried out to both help diagnose and rule out malignancies with symptoms similar to achalasia (pseudoachalasia). However, studies of esophagogastroduodenoscopy and esophagus radiographs with contrast alone can confirm only 50% of achalasia diagnosis. The diagnosis of achalasia is determined by high-resolution esophageal manometry (HRM), which is the gold standard for diagnosing achalasia.

At present, the main treatment methods for achalasia include smooth-muscle relaxants (Calcium or nitrate channel blockers), Botulinum toxin injection into the lower esophageal sphincter, balloon dilatation, and lower esophageal sphincter myotomy... While the first two methods are rarely used due to poor results and high recurrence rates, air balloon dilatation and laparoscopic myotomy are preferred treatment options because of their

effectiveness, safety, and low invasiveness. Treatment with toxin injection has a success rate of 35-41% at 12-month follow-up. Although the response rate in the first month is quite high (over 75%), this effect gradually diminishes and about 50% of patients relapse within 6-24 months and require re-treatment. Myotomy provides an 80-85% improvement in symptoms, but the risk of gastroesophageal reflux complications can also be as high as 50%, and the mortality rate is as high as 5.4%. Laparoscopic lower esophageal myotomy has also been reported to be a difficult procedure, with potentially dangerous complications such as pneumomediastinum, pneumoperitoneum, and air embolism. Meanwhile, air balloon dilatation aimed at expanding the lower esophageal sphincter is currently considered a standard, safe and highly effective method in achalasia treatment.

In Vietnam, although the authors Nguyen Thuy Oanh and Nguyen Khoi have evaluated the effectiveness of air balloon dilatation, this technique still remains unpopular and has only been utilized in a few central hospitals because the technique is fairly new and still carries the risk of esophageal perforation complications. In addition, the evaluation of treatment effectiveness by this method has not been implemented. In order to provide scientific evidence to prove the effectiveness of this treatment and widely disseminate this treatment method, we have conducted the ***"Study on clinical, paraclinical characteristics and results of achalasia treatment by endoscopic balloon"*** with the following objectives:

1. Describe clinical and paraclinical characteristics in patients afflicted with achalasia.
2. Evaluate the safety and treatment results of achalasia by endoscopic air balloon dilatation.

THESIS STRUCTURE

The thesis consists of 118 pages, of which: Thesis topic: 2 pages; Overview: 44 pages; Research subjects and methods: 11 pages; Research results: 30 pages; Discussion: 28 pages; Conclusion: 2 pages; Recommendation: 1 page.

The research results of the thesis are presented in 27 tables and 12 charts. The thesis uses 141 reference materials.

Chapter 2
RESEARCH SUBJECTS AND METHODS

2.1. Research subjects

Patients with achalasia, examined and treated at Bach Mai Hospital and 108 Military Central Hospital from January 2014 to January 2021.

2.2. Research methods

2.2.1. Research design

- Research design: Prospective study with clinical intervention and longitudinal follow-up, no control

- The research utilizes the following formula to calculate sample size to estimate a proportion:

$$n = Z^2_{1-\alpha/2}\frac{p.(1-p)}{d^2}$$

Of which:

$Z_{1-\alpha/2}$ = 1.96; p = 0.848 - is the success rate of the first esophageal dilatation by balloon [12]; d = 0.1; n = 50 patients. In fact, the study was performed on 75 patients.

- This research opted for convenient sampling method, all patients who met the selection criteria and did not fall into the exclusion criteria were selected for the study until the minimum sample size was met.

- Research diagram:

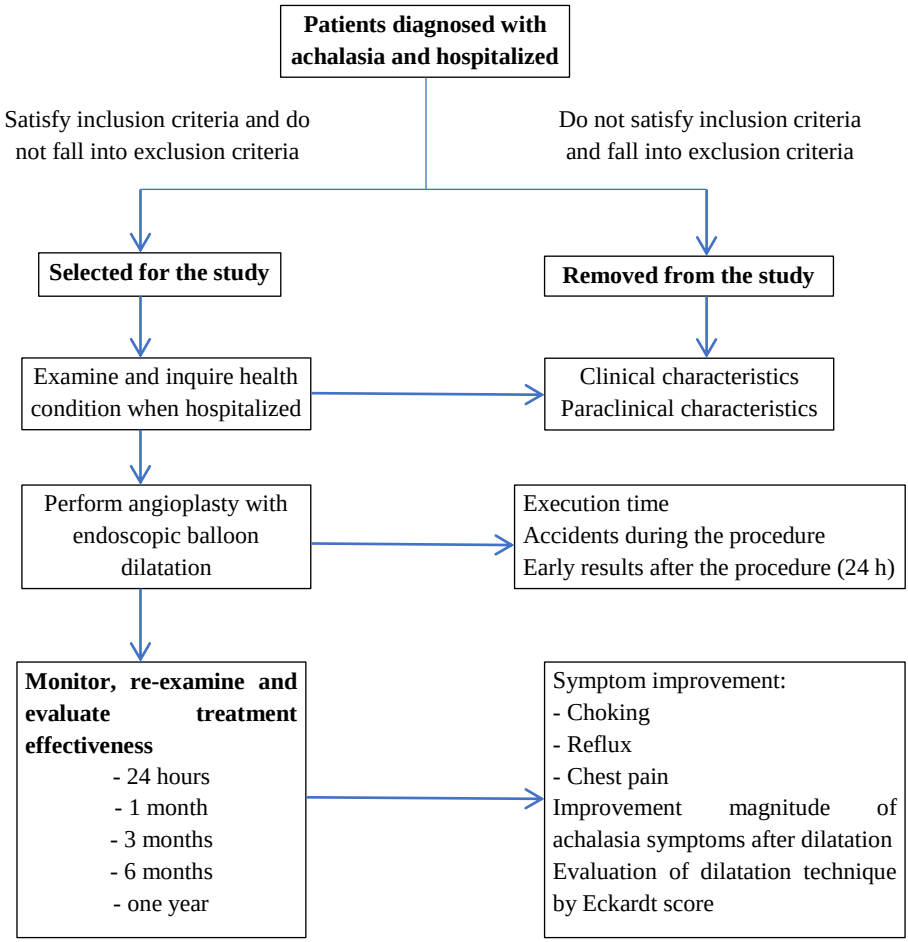


Figure 2.1. Research diagram

2.2.2. Research equipment

Various machinery and equipment: Gastric endoscope: OLYMPUS – CV180 (Japan); Rigiflex balloon with a diameter of 3.5cm made by Boston Scientific (USA); Pressure pump with gauges of Boston Scientific (USA); Noose of Olympus (Japan); Lubricant, bite gag, cotton gauze, washing solution, syringe ... used in gastrointestinal endoscopy

2.3. Research steps

Step 1: Patient screening and diagnosis

Step 2: Intervention using the balloon dilatation procedure.

Step 3: Monitor immediately after treatment.

Step 4: Longitudinal follow-up after 1 month, 3 months, 6 months and 12 months after the intervention

2.4. Research criteria

2.4.1. Clinical criteria

Clinical symptoms reported by patients include choking, reflux, and chest pain:

Table 2.1. Symptom magnitude

Symptom	Choking	Reflux	Chest pain
Magnitude	None	None	None
	Mild	Mild	Mild
	Moderate	Moderate	Moderate
	Severe	Severe	Severe
	Critical	Critical	Critical

Frequency of symptoms was scored on the Vanrtrappen scale:

In addition, the frequency of gastroesophageal reflux was assessed based on the GERDQ score:

0 points: Never happened

1 point: 1 day per week

2 points: 2-3 days per week

3 points: 4-7 days per week

+ Weight loss: Weight loss compared to before the appearance of the above clinical symptoms. Weight loss is divided into levels: under 5kg, 5-10kg and over 10kg.

+ Eckardt score:

Table 2.3. Eckardt scale

Score	Symptom			
	Weight loss (kg)	***Choking***	***Chest pain***	***Reflux***
1	0	None	None	None
2	< 5	Occasionally	Occasionally	Occasionally
3	5 – 10	Daily	Daily	Daily
4	> 10	Every meal	Every meal	Every meal

2.4.2. Paraclinical criteria

- Chest X-ray: radish/sock.

- Dilatation magnitude based on esophageal diameter measured on X-ray

2.4.3. Diagnosis

The gold standard in diagnosing achalasia is esophageal manometry. Computed tomography and esophageal endoscopy are subclinical support for the diagnosis of the disease, although neither of these methods is sufficient for a definitive diagnosis. Diagnosis was made according to 2013 American Gastroenterological Association recommendations.

2.4.4. Evaluation criteria

The assessment of systemic symptoms and complications such as bleeding, perforation, etc. was performed at the following time points: After the intervention (within 24 hours); 1 month after the intervention; 3 months after the intervention; 6 months after the intervention; 1 year after intervention.

At the mobitor time after intervention 1, 3, 6 and 12 months, re-evaluate the clinical symptoms and disease severity as follows:

✓ ***Assess symptoms***

Symptoms such as choking, reflux, chest pain are assessed based on the patient's subject point of view as follows: None: 0 points, mild: 1 point, moderate: 2 points, severe: 3 points, critical: 4

points ; Symptoms of changes in body weight (weight loss or gain); Time of illness: from the onset of choking to the time of treatment.

- ✓ ***Assess disease stages using the Eckartd scale before the procedure***
- ✓ ***Change in symptom score***
- ✓ ***Esophageal response during balloon dilatation:*** During balloon dilatation, esophageal response can be assessed based on balloon drift time, the shorter the drift time, the better the response. Magnitude levels: Under 30s; 30 - 60s; Over 60s or no lapse
- ✓ ***Symptoms after dilatation:*** After the procedure, patients were interviewed to assess the severity of symptoms compared to the time immediately after dilatation.
- ✓ ***Complications of esophageal dilatation:*** Assess the rate of complications, proximal and distal complications of esophageal dilatation.

2.5. Data processing and analysis

Data was entered using Epidata 3.1 software and processed and analyzed with STATA 12.0 software

Descriptive statistics include: frequency and percentage ratios; mean, dlc, maximum and minimum values are described.

Statistical analysis includes Chi-squarer and Fissher exact test used to compare percentage ratios, t-ttest, Kruskal wallis test and anova test used to compare mean values.

2.6. Research ethics

The study was accepted by the Association through the protocol of the Research Institute of Clinical Medicine 108.

The research is permitted by Bach Mai hospital and 108 Military Central Hospital

The obtained information is kept completely confidential and used for research purposes only.

The research does not affect the health, finance and life of the research subjects.

Chapter 3. RESULTS

During the study, we have found 75 patients afflicted with achalasia with clinical and subclinical diagnosis according to selection criteria. The research results obtained are as follows:

3.1. General patient information

The patients in the study had a mean age of 49.69 ± 15.9 years (21 - 93 years old). The research group focused on the 31-50 year old age group with 29.33% is at 31-40 year olds and 24% is at 41-50 year olds.

The male/female ratio is 34/41. Men accounted for 45.33% in the study.

3.2. Clinical and subclinical characteristics of the study subjects

3.2.1. Clinical characteristics

3.2.1.1. Reason for hospitalization

Choking was the most common reason for hospitalization, accounting for 76%, followed by vomiting/reflux accounting for 14.67%. There were 2.67% of patients admitted to the hospital due to chest pain. The remaining, 6.67% of patients admitted to the hospital due to other reasons.

3.2.1.2.

Remark:

The mean duration of affliction before balloon angioplasty was 3.5 ± 2.8 years, median = 3 years (1 month – 20 years). The rate of patients coming for balloon angioplasty after showing the first symptoms for 1 year or less was the highest with 33.33%. Only 5.33% of people have had the disease for more than 6 years.

3.2.1.3. Symptom magnitude

Table 3.4. Symptom magnitude (n=75)

Magnitude	Choking		Reflux		Chest pain	
	Quantity (n=75)	**Ratio (%)**	**Quantity** (n=75)	**Ratio (%)**	**Quantity** (n=75)	**Ratio (%)**
None	1	1,33	22	29,33	44	58,67
Mild	8	10,67	20	26,67	25	33,33
Moderate	10	13,33	10	13,33	4	5,33
Severe	11	14,67	4	5,33	1	1,33
Critical	45	60,0	19	25,33	1	1,33
Total	**75**	**100**	**75**	**100**	**75**	**100**

The number of patients with choking in critical condition accounted for 60%. More than two thirds of patients had reflux symptoms, the ratio of mild reflux was 26.67%. Less than half of the patients had chest pain. The rate of mild chest pain was 33.3% and the rate of moderate, severe and critical chest pain was 5.33%, 1.33% and 1.33% respectively.

3.2.1.4. Symptom frequency

Table 3.5. Frequency of clinical symptoms (n=75)

Frequency	Choking		Reflux		Chest pain	
	Quantity (n=75)	**Ratio (%)**	**Quantity** (n=75)	**Ratio (%)**	**Quantity** (n=75)	**Ratio (%)**
Never	1	1,33	22	29,33	44	58,67
Occasionally	10	13,33	21	28,0	28	37,33
Daily	17	22,67	24	32,0	2	2,67
Every meal/ Multiple times	47	62,67	8	10,67	1	1,33
Total	**75**	**100**	**75**	**100**	**75**	**100**

Remark:

The number of patients with choking on each meal accounted for 62.67%. The ratio of patients with daily reflux was the highest, accounting for 32.0%. Among patients with chest pain, the rate of

symptoms with low frequency (occasionally) was the highest, accounting for 37.33%.

3.2.1.5. Weight loss

80% of patients have experienced weight loss. Of which, the majority of patients lost less than 5 kg, accounting for 49.33% of the patients studied.

3.2.1.5. Disease stage according to Eckardt scale

None of the patients in the study was afflicted at stage 0 according to the disease severity by the Eckardt score. The prevalence of stage II disease was the most common with 68%, followed by stage III with 29.33%. Only 2/75 patients, accounting for 2.67%, were at stage I disease.

The mean disease duration at stage I, II and III was 5.0±1.4 years, 4.0±3.08 years and 2.18±1.59 years, , respectively. The difference was statistically significant with $p<0.01$.

3.2.2. Paraclinical characteristics

Contrast X-ray film showed that most of the patients had radish-shaped esophagus, accounting for 90.67%. The remaining 7/75 patients had sock-shaped esophagus (9.33%).

The mean duration of affliction was significantly higher in the patient group with sock-shaped esophagus compared to the radish-shaped esophagus group (8.57±5.13 years versus 2.99±1.85 years). The difference was statistically significant with $p<0.01$.

Nearly ½ of patients had grade I esophageal dilatation, accounting for 49.33%. The ratio of degree II dilatation is 37.33%. The ratio of grade III dilatation is 13.33%.

The mean duration of affliction in the patient group with grade I, II, and III esophageal dilatation was 2.19±1.75 years, 3.7±1.33 years; 7.9±4.33 years, respectively. The difference was statistically significant with $p<0.01$.

On endoscopic images, the ratio of dilated esophagus was 78.67%, fluid and food were seen in 29.33% cases, 46.67% closed when inflated and in 17.33% cases no lesion was seen.

3.3. Evaluation of endoscopic balloon dilatation treatment results in treating achalasia for above patients.

3.3.1. Intervention techniques

All studied patients were anesthetized with pre-anesthesia during balloon dilatation. None of the patients in the study received intravenous and endotracheal anesthesia.

The average inflation pressure in the study was 5.0 ± 0.7 psi, of which the patient was pumped with a minimum pressure of 3psi and maximum at 7psi. Patients in the study were pumped with a pressure of 5psi, accounting for 73.3%. Balloon inflation pressure was not different in patients with different magnitude of esophageal dilation before dilatation ($p>0.05$).

Angioplasty pressure was gradually increased for patients with more severe condition before dilatation according to the Eckardt score. The balloon inflation pressure of stage I, II and III patients was 3.5±0.7 psi, 4.93±0.69 psi and 5.2±0.43 psi, respectively. The difference was statistically significant with $p<001$.

3.3.2. Safety

The number of patients with no sign of complications after balloon angioplasty accounted for 80%. The rate of experiencing pain behind the sternum was 12%, the remaining symptoms appeared with a low rate such as vomiting (4.0%); heartburn (2.67%); fever (2.67%).

3.3.3. Treatment effectiveness

3.3.3.1. Early treatment effectiveness after 24 hours

Even during balloon dilatation, the percentage of patients with the balloon drifting on its own for more than 1 minute or not, the ball drifting after 30-60 seconds and less than 30 seconds, was 41.33%, 33.33% and 25.33%, respectively.

The percentage of patients with spontaneous balloon drift time of less than 30 seconds was highest in the group of grade III esophageal dilation (40%). And the spontaneous balloon drift time of over 60 seconds is the highest in the grade I dilation group at 45.95%. However, the difference in spontaneous balloon drift time

and esophageal dilation before dilatation was not statistically significant with p>0.05.

3.3.2.2. Treatment results 24 hours after dilatation

Immediately 24 hours after dilatation, 72% of the studied patients no longer experince choking. The percentage of mild and moderate choking were 21.33% and 6.67%. There was no patient with severe and critical choking.

The percentage of patients who no longer experince choking 24 hours after dilatation was highest in the group of grade I dilation (100%) and lowest in the group of grade III dilation (40.0%). In contrast, the percentage of moderate choking was highest in the group of grade III dilation and there were no patients with moderate choking in group I and II before dilatation.

3.3.3.3. Degree of clinical symptoms

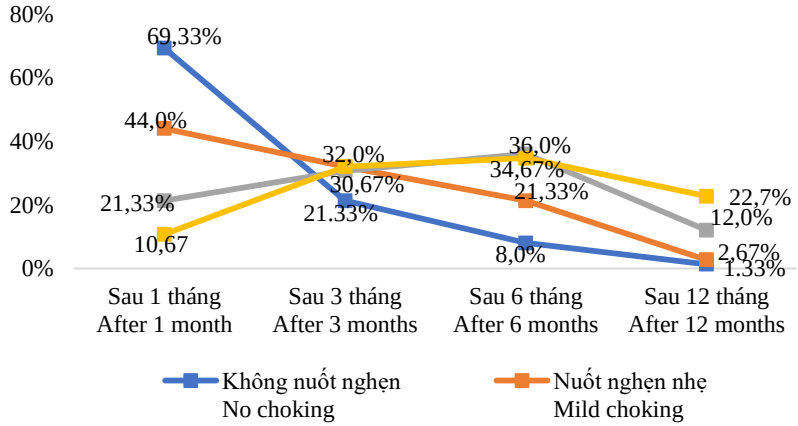


Chart 3.5. Degree of choking after dilatation during monitoring (n=75

The percentage of no choking after dilatation 1 month, 3 months, 6 months and 1 year respectively was 69.3%; 21.3%, 8.0% and 1.3%. In contrast, the percentage of severe choking increased from 10.7% after dilatation 1 month to 22.7% after dilatation 1 year.

Choking symptom score at the time after dilatation was lower than before, statistically significant. The average symptom score of choking symptoms decreased sharply after 1 month, from 3.2 ± 1.1 to 0.4 ± 0.7; then gradually increased over time, to 1.7 ± 0.9 after dilatation 12 months (p<0.01).

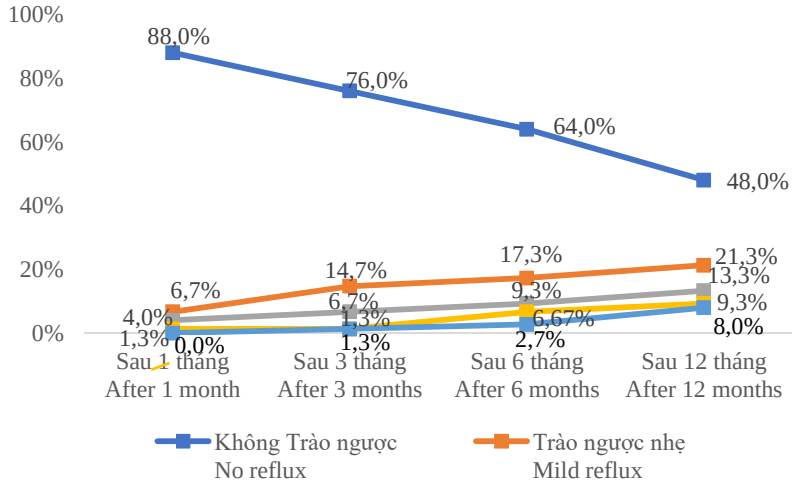
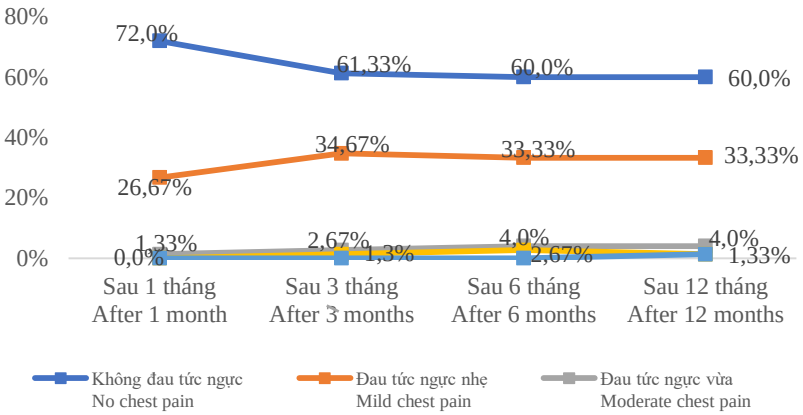


Chart 3.6. Degree of reflux after dilatation during monitoring (n=75)

The percentage of no reflux tends to decrease sharply over time, from 88% after dilatation 1 month to 48% after 1 year. The percentages of choking at different degrees gradually increased during monitoring period.

Reflux symptom scores at the time after dilatation were lower than before, statistically significant. The mean score of choking symptoms decreased sharply after 1 month, from 1.7 ± 0.2 to 0.2 ± 0.6; then gradually increased over time, to 1.1 ± 0.2 after dilatation 12 months (p<0.01).



Biểu đồ 3.1. Mức độ đau tức ngực sau nong trong thời gian theo dõi (n=75)

Chart 3.7. Degree of chest pain after dilatation during monitoring (n=75)

Sau 1 tháng nong bóng, có 72% số bệnh nhân không đau tức ngực, tỷ lệ này từ sau 6 tháng chỉ còn 60%. Các mức độ đau tức ngực cũng tăng dần tỷ lệ khi thời gian theo dõi tăng lên.

After 1 month of balloon angioplasty, 72% of patients did not experience chest pain, this rate dropped to 60% after 6 months. The severity of chest pain also increased in proportion as the monitoring time increased.

Điểm triệu chứng đau tức ngực sau nong 1 và 3 tháng là 0,3 ± 0,5 và 0,4 ± 0,6 thấp hơn có ý nghĩa thống kê so với trước nong là 0,5 ± 0,8. Tuy nhiên từ sau 6 tháng, kết quả không có khác biệt đáng kể so với trước nong (p>0,05).

The symptom score of chest pain after dilatation 1 and 3 months is 0.3 ± 0.5 and 0.4 ± 0.6, which is statistically significantly and lower than before, which is 0.5 ± 0.8. However, after 6 months, the results were not significantly different from before (p>0.05).

After 1 month of esophageal dilatation, the majority of patients did not gain weight (73.4%). The percentage of weight gain under

5kg was 25.3% and only 1/75 of the patients gained from 5-10kg. After 3 months of esophageal dilatation, 65.3% of patients gained weight, the percentage of gaining less than 5kg, 5-10kg and over 10kg compared to before dilatation was 41.3%, 22.7% and 1.3%, respectively. After 6 months of balloon angioplasty, the percentage of patients gaining weight was 78.7%, of which 48% of patients gained less than 5kg, 27.7% of patients gained 5 - 10kg and 3/75 patients gained more than 10kg, accounting for 4% of patients studied. After 12 months of esophageal dilatation, 13.3% of patients did not gain weight, the percentage of gaining less than 5kg, 5-10kg and over 10kg compared to before dilatation was 52.0%, 24.0% and 10.7%, respectively.

3.3.3.2. Frequency of clinical symptoms over time

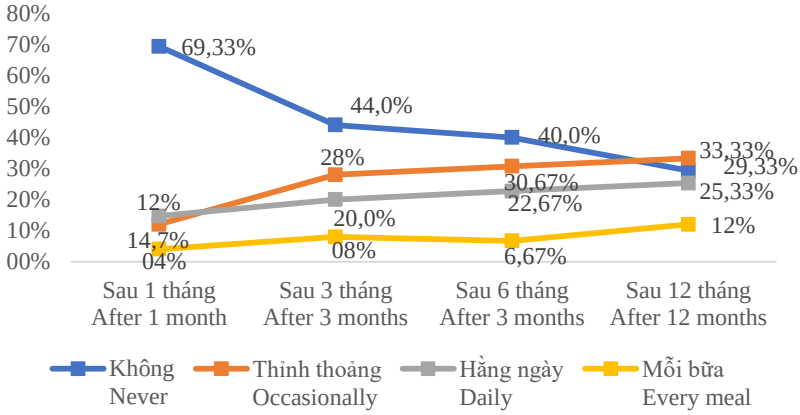


Chart 3.8. Frequency of choking after dilatation during monitoring (n=75)

The percentage of patients with occasional choking increased from 14.7% after dilatation 1 month to 33.33% after dilatation 1 year. Similarly, the percentage of daily choking was 14.7%,

increased to 25.33% and the percentage of choking every meal was increased from 4.0% to 12%.

The frequency score of choking decreased sharply from 2.5±0.8 to 0.5±0.9 after 1 month and then gradually increased to 1.2±1.0 after 1 year. At all monitoring points, the frequency score of choking after dilatation decreased significantly compared to before dilatation.

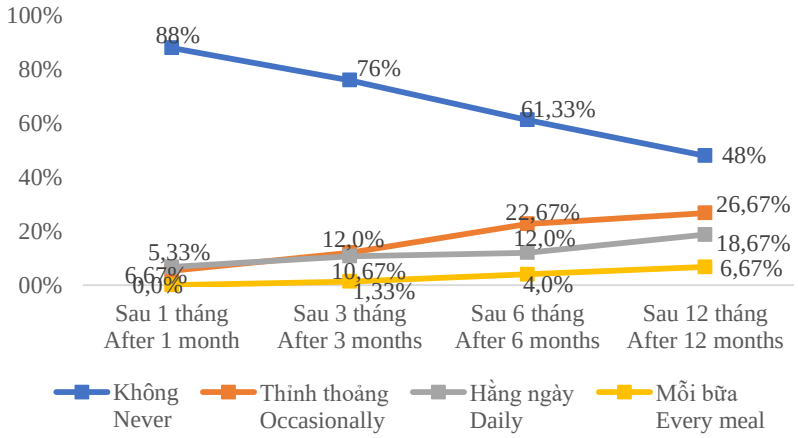


Chart 3.9. Frequency of reflux after dilatation during monitoring (n=75)

The percentage of occasional choking increased from 5.33% to 26.67%; daily choking percentage increased from 6.67% to 18.67% and choking every meal percentage increased from 0% to 6.67%.

Reflux frequency score decreased sharply from 1.2±1.0 to 0.2±0.5 after 1 month and then gradually increased to 0.8±1.0 after 1 year. At all monitoring points, the post-dilatation reflux frequency score decreased significantly compared to pre-dilatation.

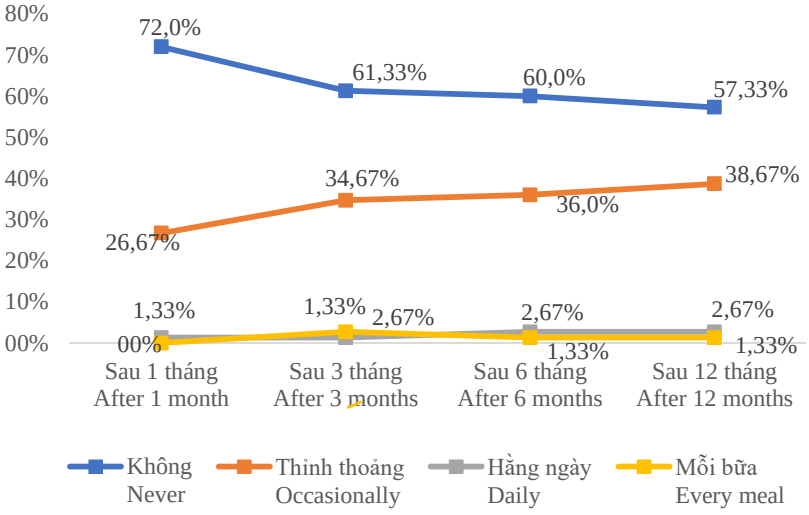


Chart 3.10. Frequency of chest pain after dilatation during monitoring (n=75)

The percentage of patients with occasional chest pain increased from 26.67% after dilatation 1 month to 34.67%; 36% and 38.67% after dilatation 3, 6 and 12 months. The percentage of daily chest pain after dilatation 3 months did not change compared to after 1 month point of 1.33%, then increased to 2.67% from 6 months to 1 year. After balloon angioplasty 1 month, there were no patients with chest pain every meal/several in a day, after 3 months, this percentage was 1.33%.

The frequency score of chest pain decreased from 0.5±0.6 before dilatation to 0.2±0.5 after dilatation 1 month. After dilatation 3 months, the frequency score of chest pain symptoms increased again and there was no significant difference compared to before dilatation.

3.3.3.3. Results of treatment measured by Eckardt score after esophageal balloon dilatation

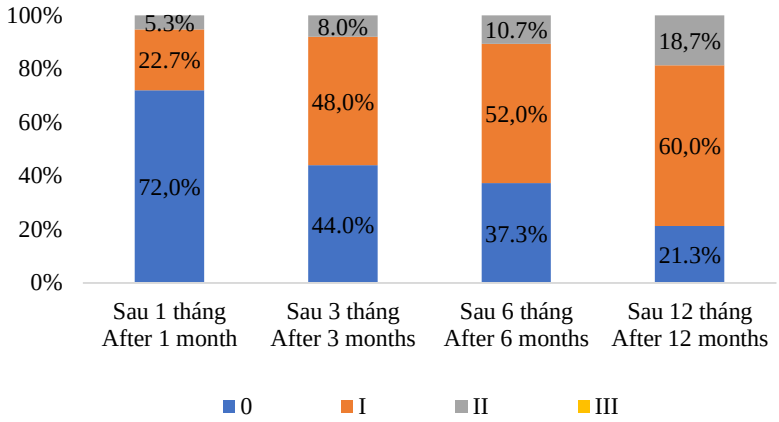


Diagram 3.11. Disease severity according to Eckardt score after dilatation (n=75)

The rate of disease level 0 according to Eckardt score gradually decreases when the follow-up time increases, from 72% after 1 month to 21.3% after 1 year. In contrast, the rate of disease level 1 and 2 tends to increase gradually over time.

Eckardt score before dilation is 5.4±1.5, statistically significantly higher than the one-month post-dilatation result of 1.0±1.2, a decrease of 4.4±1.5 ($p< 0.01$). After 3 months of dilatation, the average Eckardt score is 1.7±1.3, a statistically significant decrease of 3.6±1.8 compared to that before dilatation ($p<0.01$). After 6 months of dilatation, the average Eckardt score is 2.0 ± 1.2, a statistically significant decrease of 3.4 ± 2.0 compared to that before dilatation ($p<0.01$). After 12 months of dilatation, the average Eckardt score was 2.5 ± 1.3 points, a statistically significant decrease of 2.8 ± 1.9 compared to that before dilatation ($p<0.01$).

3.3.3.4. General treatment results after esophageal balloon dilatation

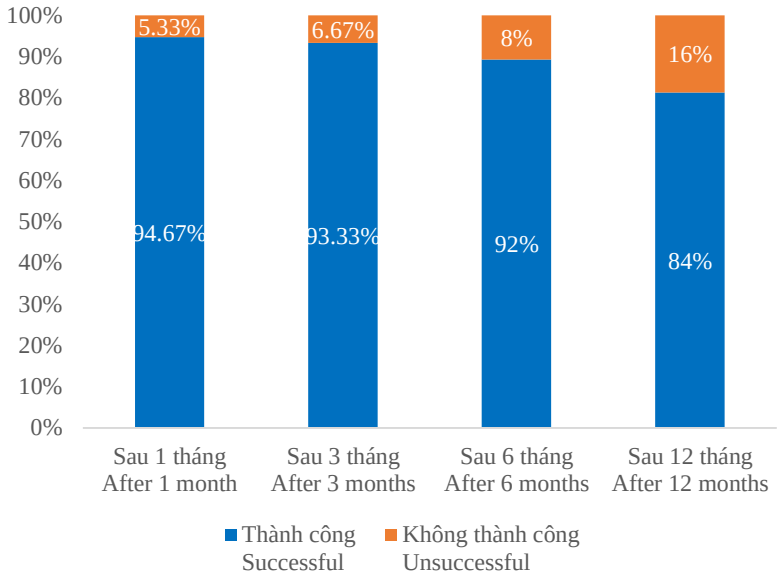


Diagram 3.12. Results of treatment after dilatation (n=75)

Most patients have successful treatment results after dilatation, this rate, after 1 month, 3 months, 6 months and 12 months of esophageal dilatation, respectively, is 94.67% and 93.33%, 92% and 84%.

3.3.3.5. Factors associated with the efficiency of treatment to 12 months

Table 3.27. The relationship between the results after 12 months of balloon dilatation with the characteristics of the research subjects (n=75)

Characteristics		Unsuccessfu		Successful		p
		Q.ty n=14	Rate (%)	Q.ty n=61	Rate (%)	
Age	21-30	1	25,0	3	75,0	0,62
	31- 40	3	13,6	19	86,4	
	41-50	3	16,7	15	83,3	
	51-60	3	37,5	4	62,5	
	>60	4	17,4	19	82,6	
Gender	Nam Male	7	20,6	27	79,4	0,70
	Nữ Female	7	17,1	34	82,9	
Duration of disease	≤1 năm/year	0	0	25	100	**<0,01**
	1 – 3 năm/ years	1	7,1	13	92,9	
	4 – 6 năm/ years	10	31,3	22	68,8	
	>6 năm/ years	3	75,0	1	25,0	
Pre-dilatation class	I	1	50,0	1	50,0	0,43
	II	10	19,6	41	80,4	
	III	3	13,6	19	86,4	
X-ray image	Củ cải Radish	8	11,8	60	88,2	**<0,01**
	Bít tất Sock	6	85,7	1	14,3	
Esophageal dilatation	I	4	10,8	33	89,2	0,36
	II	6	21,4	22	78,6	
	III	4	40,0	60,0	70,0	
		TB	**dlc**	**TB**	**Dlc**	**p**
Average age (age)		50,9 ±16,5		49,4±15,9		0,76
Disease duration (years)		6,4±4,2		2,9±1,9		**<0,01**

The rate of successful treatment in the group with less than 1 year of disease is 100%, while in the group with more than 6 years of disease, it is only 25.0%. The average duration of disease in the successful treatment group is 2.9±1.9 years, significantly lower than that in the unsuccessful group, which is 6.4±4.2 years. The difference is statistically significant with $p<0.01$. The rate of successful treatment in the group with radish-shaped esophagus before the procedure is 88.2%, statistically significantly higher than the group with sock-shaped esophagus as 14.3% ($p<0.01$).). Before the procedure, the group of patients with more severe esophageal expansion has a lower success rate of esophageal dilatation, the success rate in the group of dilatation level I is 94.6%, while this rate in the group of dilatation level III is only 70 %. The average age of the group of patients successfully treated up to 12 months is 49.6±15.9 years old, lower than the unsuccessful group of 50.9±16.5 years. However, there is no statistically significant difference.

CONCLUSION

1. Clinical and subclinical characteristics of achalasia patients at Bach Mai hospital and 108 Military Central Hospital.

Clinical characteristics

- Reason for hospitalization: choking (76%), vomiting/reflux (14.67%). Other causes such as chest pain, bloody stools, weight loss, etc. are less common.

- The average duration of disease is 3.5 ± 2.8 years (1 - 20 years). The rate of less than 1 year is 33.3%; 1 - 3 years is 18.7%; and 4-6 years is 24.7%.

- Clinical symptoms: choking (98.67%), reflux (70.67%) and the rate of chest pain accounting for 41.33%.

- The rate of mild chest pain (33.33%), but the rate of choking is 60%l and the rate of very severe reflux is 25.33%. The frequency of

daily and per-meal choking (22.67% and 626.7%), daily and per-meal reflux rates are 32.0% and 10.67% respectively. This rate for chest pain is 2.67% and 1.33%.

- 80% of patients have weight loss, 49.33% of patients lose less than 5kg, 12% of patients lose more than 10kg.

- The classification at stages II and III according to Eckardt scale is 68% and 29.33%.

Subclinical characteristics

- X-ray images of the esophagus shows the shape of a radish (90.67%), the rest has the shape of a sock. Patients with sock-shaped esophagus had a longer disease duration (8.6±5.1 years versus 3.0±1.8 years).

Patients with esophageal dilatation level I is 49.33% and level II is 37.33%. The average duration of disease in the group of patients with esophageal dilatation level I, II, and III is 2.2±1.7 years; 3.7±1.3 years; 7.9±4.3 years, respectively. The difference is statistically significant with $p<0.01$.

2. Evaluation of safety and results of esophageal balloon dilatation in the treatment of achalasia.

Safety

- 80% of patients have no complications after balloon dilatation. The rate of having pain behind the sternum is 12%, the remaining symptoms appear with a low rate such as vomiting (4.0%); burning (2.67%); fever (2.67%).

Efficiency of treatment

The treatment is effective in reducing the rate of symptoms after 1-3 months, but the severity and frequency of symptoms tend to increase gradually during long-term follow-up:

- Choking decreases after 24 hours of balloon dilatation (72% of patients did not choke).

- Both severity and frequency of choking and reflux

significantly reduces at 1, 3, 6 and 12 months after dilatation compared to that before dilatation. The frequency and severity of choking and reflux tend to increase again after a longer time. Choking score after intervention is 0.4±0.7; 0.8±0.9; 1.4 ± 1.0 and 1.7 ± 0.9, respectively. Choking frequency score is 0.5±0.9; 0.9±1.01.0±1.0 and 1.2±1.0.

- The degree of chest pain decreases significantly after balloon dilatation compared to before (the rate of severe chest pain before, immediately after, after 1 month, 3 months, 6 months and 12 months is 1.33%; 0%; 1, 33%; 2.67%; and 1.33% (and 1.33% very severe), however, the frequency of chest pain decreases only in the first month, at 3 months, 6 months, and 12 months after dilation, the frequency of chest pain increases again.

- The efficiency of treatment assessed by Eckardt score is 94.67% after 1 month of dilation, reduces to 93.33% after 3 months and to 92% and 84% respectively after 6 and 12 months, indicating the risk of recurrence and decreased efficiency of treatment over time.

- The group of successful treatment has an average disease duration of 2.9±1.9 years, the group of unsuccessful treatment is 6.4±4.2 years.

RECOMMENDATIONS

- The esophageal balloon dilatation is a safe and effective method of choice for patients with achalasia, and is developed in lower-level units.

- Treatment should be carried out for patients with achalasia who have symptoms affecting their quality of life or health as soon as possible to achieve the optimal efficiency of treatment.

- However, the method effect does not last long, it is necessary to monitor patients and continue to research more optimal solutions.

- Further longer-term follow-up researches are needed to evaluate the long-term effectiveness of the treatment method.