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PREDICTIVE FACTORS OF OUTCOME OF PNEUMATIC DILATION IN ACHALASIA

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ABSTRACT

Introduction: Endoscopic balloon dilation (EBD) remains an essential option for treatment of achalasia. Success rate is variable depending on the study. The aim of our study was to identify predictive factors of outcome after endoscopic dilatation for primitive achalasia. **Patients and Methods:** Retrospective study involving patients with achalasia treated by endoscopic balloon dilatation from January 2002 to January 2016 were included. A follow up period of at least 6 months after EBD was required. Balloon dilatation was performed with Rigiflex® 30 or 35mm balloon. Criteria for failure of EBD were defined by need forrecourse toa second session of dilatation or Heller cardiomyotomy. **Results:** During the studied period, 120 pneumaticdilationswere performed. 100 patients whose follow-up was available for at least 6 months were included. Sex ratio was 1.12 [M /F =53/47] and average age was 42 +/- 17 years [7-88]. A recurrence of symptoms was observed in 36% of cases after the first session of endoscopic dilatation justifying a second endoscopic dilatation(in 36 cases) or surgical treatment (Heller's cardiomyotomy) (in 6 cases). The recurrence of symptoms occurred within 5.1 +/- 3 months [1-12 months].Predictors of failure of PD were age <30 years (p =0.01), male gender (p = 0.003), vigorous achalasia (p <0.0001) and an initial PSIO<30mmHg (p=0.01). In multivariate analysis male gender (p<0,001) and vigorous achalasia (p<0,001) were independent predictors of failure of EBD. **Conclusion:** Independent predictive factors of poor response to endoscopic dilatation in our cohort were clinical (male gender) and manometric (vigorous achalasia). This could suggestto use another technique such as per oral endoscopic myotomy if these factors are present**.**

KEYWORDS: achalasia, pneumatic dilation, predictive factors.

INTRODUCTION

Achalasia is characterized by functional obstruction of the esophagus secondary to a lack of relaxation associated with an aperistaltism of the body of the esophagus in manometry.[1] Treatment options are well known: pharmacologic treatment (such as nitrates, calcium channel blockers), endoscopic treatment (including injection of botulinum toxin and pneumatic dilation) or surgical treatment (Heller's cardiomyotomy).[2] More recently, a new endoscopic technique, per oral endoscopic myotomy (POEM), showed an excellent short-term symptomatic efficacy and lasting success rate.[2]

In practice, pneumatic dilation is the most frequently used with a success rate ranging between 35 and 85% depending on the series.[3] Several studies have identified predicting factor of clinical outcome following endoscopic dilatation.

The aim of this study was to identify predictors of failure of endoscopic treatment in primary achalasia in our experience.

PATIENTS AND METHODS

PATIENTS: From 2002 to 2016, 120 patients were addressed to perform endoscopic dilatation for primitive achalasia. Diagnosis of achalasia was based on results of upper endoscopy and manometry showing an aperistaltism of esophageal body and a lack of relaxation of lower esophageal sphincter. The low sphincter pressure of the esophagus (LES) was specified. A timed barium oesophagram was realizedin order to appreciate the esophagus dilatation. We included in our study, patients with a follow up upper to 6 months.

One hundred patients (53 men and 47 women), mean age 42 +/- 17 years (range 7-88) were included. Twenty patients, with a follow up lower than 6 months were excluded from the study.

Failure in outcome of the pneumatic dilatation was defined by need fora second session of dilatation or Heller cardiomyotomy because recurrence of symptoms.

METHODS

Endoscopic pneumatic dilatation was performed under sedation, using a Rigiflex® balloon with a diameter of

30 or 35mm *(fig 1)* and a pressure depending on the endoscopist during 2 minutes on average. Balloon was positioned at the gastrooesophageal junction and inflated under fluoroscopic guidance *(fig 2).*

Patients were systematically hospitalized during the 24 hours following the endoscopic procedure in order to detect possible complications.

Statistical study

Statistical analysis was performed using SPSS. 21 software. Comparison of variables was performed according to Pearson chi^2 test for qualitative variables and Student's t test for quantitative variables. A logistic regression was performed to determine independent predictive factors of failure of EBD. A combination of variables was considered statistically significant if p value was less than 0.05.

RESULTS

One hundred patients with primitive achalasi atreated bypneumatic dilation with an average follow-up of 12 months [6-60 months]were included.

Endoscopic characteristics: Upper endoscopy showed an esophageal stasis in 71 cases, adifficulty of crossing LES was noted in 81 patients. An associated esophagitis was noted in 3 cases. Other lesions were noted in 17 cases including bulb ulcer in 7 cases, congestive antral gastropathy in 9 cases, and aberrant pancreas in 1 case.

Radiologic characteristics: Timed barium oesophagram was available in 82 patients. It showed an esophageal diameter less than 4 cm (stage I) in 35cases, between 4 and 6 cm (stage II) in 37cases and more than 6 cm (stage III) in 10 cases.

Manometric characteristics: Mean LES pressure was 34 mm Hg [range 8 - 150 mm Hg]. LES pressure was upper to 30 mmHg in 54cases. Amplitude of esophageal contractions averaged 62 mm Hg [0-195]. A high pressure upper to 150 mm Hg (defining vigorous achalasia) was observed in 27 cases.

Endoscopic dilatation characteristics: Pneumatic dilation was performed with a 35 mm balloon in 41%, and 30 mm in 59% of cases.The mean pressure of dilatation was 10.2 PSI [range 7-50]. No immediate complication occurred during procedure.

Follow-up after dilatation: Endoscopic dilatation had a success rate (no recurrence of symptoms) in 67% of cases with a mean follow up of 12 months.[6-60]

In 36 cases, no response (12 cases) or recurrence of dysphagia (24 cases) were noted. Average time of recurrence of symptoms was 5.1 months [1-12 months].

Twenty nine patients underwent a control manometry. Mean LES pressure was 23 mm Hg [9-60 mmHg]. A decrease compared to the initial LES pressure was noted in 18 cases with a mean decrease of 6 PSI [1-18]. In 11 patients, manometry showed an increased LES pressure in comparison with the initial value (mean 5 PSI [1-14]).

A second session of endoscopic dilatation was performed in all patients with failure after first dilatation (n=36). A success rate after a second endoscopic dilatation was noted in 31 cases. Five patients underwent more than two sessions of endoscopic dilatation [range 3-4]. Surgical treatment(Heller'scardiomyotomy) was performed in5 cases. Post dilatation follow-up is reported in *fig 3.*

Predictors factors of failure to endoscopic dilatation: Predictive factors of outcome of pneumatic dilatation in our study were age <30 years (p =0.01), male gender (p = 0.003), vigorous achalasia (p <0.0001) and an initial PSIO<30mmHg (p=0.01). In multivariate analysis male gender (p<0,001) and vigorous achalasia (p<0,001) were independent predictors of failure of EBD.

Predictive factors of failure of pneumatic dilatation are summarized in *table 1.*

FIGURES

Figure 1: Rigiflex® dilation ballon.

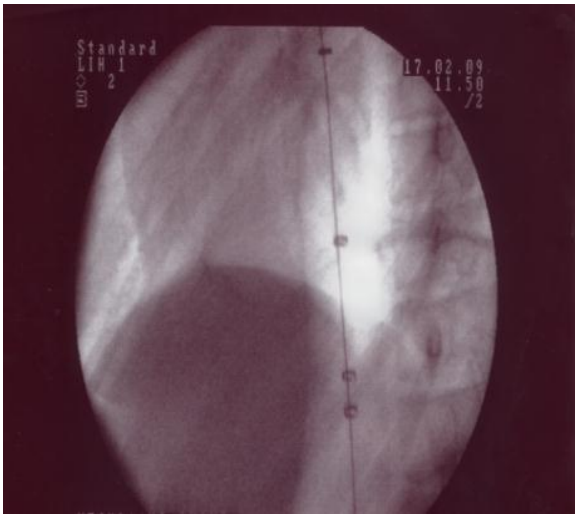

Figure 2 : Dilation ballon visualised under fluoroscopic guidance.

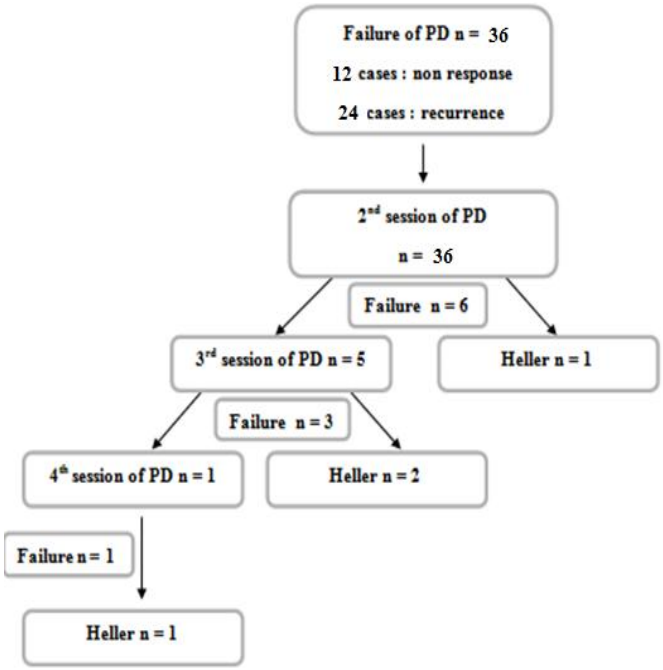

Figure 3: Distribution ofpatientsaccording to type ofsecondary treatmentafter non response or symptomatic recurrence.

Table 1: Predictive factors of outcome of pneumatic dilatation.

Characteristics		n =	Failure	No failure	p value
Clinicalcharacteristics					
Sex	M	53	29	24	0.001
	F	47	10	37	
Age	<30years	29	14	15	0.03
	≥30years	71	25	46	
Endoscopic characteristics					
Dilatation of the oesophagus	Yes	39	17	22	0.074
	No	61	29	32	
Stasis	Yes	71	20	40	0.317
	No	29	10	14	
Difficulty of crossing LES	Yes	81	33	48	0.32
	No	19	9	10	
Œsophagitis	Yes	3	2	1	0.29
	No	97	37	63	
Radiologic characteristics					
Oesophageal dilatation > 6cm	Yes	10	5	5	0.325
	No	90	42	48	
Manometric characteristics					
Initial LES pressure	<30 mm Hg	46	24	22	0.001
	>30 mm Hg	54	12	42	
Initial amplitude of oesophageal body contractions	<150 mm Hg	73	21	52	<0.0001
	>150 mm Hg	27	21	6	
Technical characteristics					
Pression of dilatation	≤ 10 PSI	64	34	30	0.283
	>10 PSI	36	26	10	
Balloon diameter	30 mm	41	12	29	0.154
	35 mm	59	24	35	

Table 2: Summary of predictors of outcome ofPneumatic Dilation during achalasia found in the different studies (4).

Author and Year	Number of patients	Type of Study	Predictors of outcome of Pneumatic dilation
Eckardt and al, 1992	54	Prospective	Age, balloon diameter and post-PD LES pressure
Ponce and al, 1996	157	Prospective	Age, sex, esophageal bodydiameter and basal LES pressure
Vaezi and al, 2004	75	Retrospective	Age, sex and timed barium esophagogram
Mehta and al, 2005	52	Retrospective	Age
Ghoshal and al, 2004	126	Retrospective	Sex and post-PD LES pressure
Chuah and al, 2009	32	Prospective	Age
Our study	100	Retrospective	Age, sex, LES pressure, vigorous achalasia and low pressure of dilation

DISCUSSION

In our study, the success rate of pneumatic dilation during achalasia was 64%. Predictive factors of outcome of pneumatic dilatation were age <30 years, male gender, vigorous achalasia and an initial PSIO<30mmHg.

Authors report asuccess rate ranging from 35 to 85%.[1-4] Main factors identified include clinical factors (such as young age <40 years, and male sex[4], and also important duration of symptoms before treatment[5]), manometric factors (such as a low oesophageal sphincter pression upper to 10mm Hg after pneumatic dilatation, and vigorous achalasia)[6], radiological factors (such as dilated esophagus on timed barium oesophagram which seem to be a factor of poor response to endoscopic treatment)[7] but also technique factors, including high pressure dilatation and a high diameter of the balloon.[3]

In our study, we reported a retrospective study of 100 patients who underwent pneumatic dilation for achalasia.

Our study confirms that a younger age is a factor predicting the outcome of endoscopic treatment during primitive achalasia and also shows that male gender is associated with a higher rate of recurrence of symptoms after the first session of pneumatic dilatation. This difference related to age and gender could be explained by the smooth muscle of the lower esophageal sphincter which may be more developed and thick in the young male and becomes finer and less tonic in older people.[8]

This could also explain the association between an initial hypotonic lower esophageal and a higher rate of recurrence after pneumatic dilation in achalasia.[9] More of this, a high pressure of esophageal contractions, (defining vigorous achalasia) represents an important predictor of outcome of pneumatic dilatation.[10] This factor was objectified in our study.

In addition, a dilated esophagus on timed barium oesophagram, could also be a predictive factor of failure of pneumatic dilation in primitive achalasia. This factor was however not found in our study despite the availability of timed barium oesophagram in 82 cases.

Regarding the technical factors of endoscopic dilation, our study found no correlation between a possible failure of endoscopic dilatation and diameter of the balloon dilatation. However, pneumatic dilatation performed at higher pressures (superior to 10 PSI) can reduce the failure rate after endoscopic dilatation. But using higher dilation pressure is also associated with a relatively more important complications rate such as perforation and bleeding.[11] This factor should therefore be considered with caution and risk- benefit balance must be studied case by case in order to indicate the best treatment option for each patient.

Many studies have attempted to determine predictive factors of outcome of endoscopic treatment during achalasia (4). The predictors of outcome of pneumatic dilation objectified in these different studies and in our cohort are resumed in table 2 (4).

Surgery, which consists on extra mucosal Heller's cardiomyotomy was classically indicated when pneumatic dilation failed. Recently, a new technique of endoscopic treatment for achalasia called peroal endoscopic myotomy showed an excellent short-term symptomatic efficacy and lasting success rate (between 91 and 100%)[12] and may than constitute an alternative for the management of achalasia.[13] This technique should therefore be discussed instead of surgery especially if predictive factors of poor response of pneumatic dilation are present and should be developed in Tunisia.

CONCLUSION

Despite the fact that pneumatic dilation is an effective,secure and recognized treatment for primitive achalasia, the risk of recurrence of symptoms after endoscopic dilation remains important. Young age, male

sex, low initial pressure of lower sphincter oesophagus, vigorous achalasia with high pressure esophageal contractions and low pressure of dilation are important predictive factors of failure of pneumatic dilatation in our study. Ifthese factors are present, surgical treatment by either peroral or surgical cardiomyotomy should be preferred. Introduction of per oral endoscopic myotomy in our country should be suggested.

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