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Argon Plasma Coagulation of Gastric Inlet Patches for the Treatment of Globus Sensation: It Is an Effective Therapy in the Long Term

P. Klare[a] A. Meining[a] S. von Delius[a] P. Wolf[b] B. Konukiewitz[c] R.M. Schmid[a] M. Bajbouj[a]

[a]Department of Medicine II, [b]Institute of Medical Statistics and Epidemiology, and [c]Institute of Pathology, Klinikum rechts der Isar, Technical University Munich, Munich, Germany

Key Words
Globus sensation · Argon plasma coagulation · Inlet patches · Long-term outcome · Reflux

Abstract
Aim: To determine the long-term effect of argon plasma coagulation (APC) of gastric inlet patches in the cervical esophagus for patients suffering from globus sensation. ***Methods:*** We intended to follow up all patients between 2004 and 2011 (n = 49) who received argon plasma ablation of gastric inlet patches for globus sensation at our clinic. Symptoms were assessed by a visual analogue scale (VAS) in 31 of 49 patients. Follow-up endoscopy of the upper gastrointestinal tract was performed to confirm residual or relapsed cervical inlet patches. ***Results:*** After a median period of 27 months, APC was assessed as a successful therapy in 23 of 31 patients (74%). VAS scores decreased significantly from 7.6 to 4.0 in the long term. Twenty-two of 31 patients were willing to undergo follow-up endoscopy. Endoscopy revealed recurrent/residual gastric inlet patches after APC in 11 of 22 cases. These patients suffered from a significant relapse of symptoms in the postinterventional period ($p < 0.001$). ***Conclusion:*** This retrospective study indicates that APC of gastric inlet patches for the treatment of globus sensation might be a sufficient therapy option. Recurrences or residual heterotopic gastric mucosa are possible and seem to be associated with a relapse of symptoms. Therefore, endoscopic follow-up and retreatment might be necessary if globus sensation is not sufficiently eliminated.

Introduction

Globus sensation is defined as a painless sensation of a foreign body in the throat which lasts for at least 3 months without a verification of structural or functional disorders of the esophagus [1]. Globus sensation has often been described as a result of psychosomatic diseases in the past [2–4], but more recent data has raised doubt about the credibility of this understanding of the phenomenon [5]. In fact, a multitude of organic disorders have been discussed as possible causes of globus sensation. Many authors have postulated a correlation between globus sensation and gastroesophageal reflux disease [6, 7], and there is some evidence that a certain proportion of patients benefit from proton pump inhibitor (PPI) therapy [8]. On the other hand, there is also evidence that globus sensation is not related to gastroesophageal reflux disease and many patients complain about persistent symptoms despite taking PPIs [9, 10]. In fact, the underlying cause of this complaint has not yet been identified unambiguously. Recently, cervical inlet patches (CIP)

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Monther Bajbouj, Dr. PD
II. Medizinische Klinik, Klinikum rechts der Isar
Ismaninger Str. 22
DE–81675 München (Germany)
E-Mail monther.bajbouj@lrz.tum.de

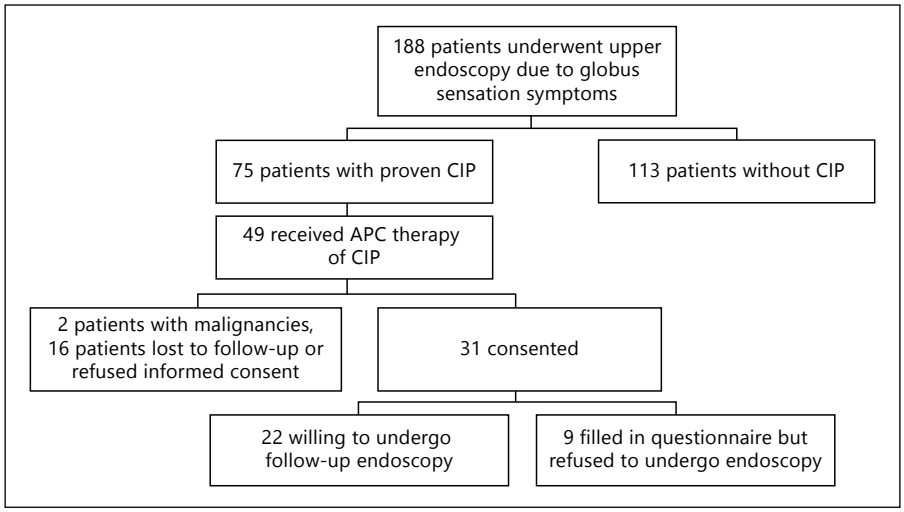

Fig. 1. Patient flow diagram for clinical and endoscopical data collection.

have been linked to globus sensation [11, 12]. CIP can be found in up to 11% of patients undergoing upper endoscopic procedures, and the majority of cases is free of symptoms and have no related symptoms [13, 14]. In very few patients, in the literature only presented in form of case reports, complicated courses can develop out of CIP and may lead to a wide clinical spectrum ranging from ulcers, strictures, perforation, fistulas or at worst the development of adenocarcinomas in the esophagus [15–18]. In a feasibility study and a consecutive sham-controlled study we were able to show that an endoscopic ablation of inlet patches using argon plasma coagulation (APC) led to significant short-term symptom relief of globus sensation [10, 19]. However, there are no data on long-term outcomes in these patients. Therefore, we aimed to assess data focusing on the clinical and endoscopic long-term value of prior APC of CIP for the treatment of globus sensation.

Patients and Methods

Selection of Patients

We consulted the in-house database of our endoscopy department in order to detect all globus sensation patients who received APC therapy of histologically proven CIP with the aim of alleviating respective symptoms between 2004 and 2011. Subjects were considered if globus sensation was formerly described by the patient as the feeling of a lump in the throat, hoarseness, a sore throat or the necessity of clearing the throat frequently. Database query revealed a total of 188 patients receiving upper gastrointestinal endoscopy due to globus in the 8-year time period. Seventy-five patients (40%) revealed CIP and were therefore advised to undergo APC therapy. Forty-nine patients actually used APC in a following session. Some patients had received APC in a former trial investigating the general effectiveness of APC in the treatment of globus [10]. Those patients who were randomized in the control arm of the study initially received placebo, but were treated with APC in a second session after completion of the mentioned trial. Ablation was performed using ERBE ICC 300 (Erbe GmbH, Tübingen, Germany) with a power configuration of 60 W, and argon flow was set to 2 l/min. All endoscopists used a straight cap (distance-cap; 4-mm rigid type) while applying coagulation in order to better control the desired area. The performance of APC for alleviating globus sensation was the criterion of inclusion in this survey. Two patients were excluded because of underlying malignancies of the upper gastrointestinal tract. Patients with a history of reflux disease were not excluded generally. These patients were considered suitable for inclusion if a 4-week course of PPI treatment prior to the APC therapy led to no substantial improvement of globus sensation symptoms. We contacted all patients by phone and invited them to the follow-up examination. In cases where telephone contact was not successful, a written invitation was sent out. Seven patients denied consent and 9 patients were not reachable by phone or postal service. Thus, 31 of the 49 previously treated patients gave written consent to participate in this follow-up study. Of those 31 patients, however, only 22 were willing to undergo endoscopy in addition to an assessment of their symptoms (fig. 1). Patient characteristics of all participating subjects are shown in table 1.

The study was approved by the ethics committee of the Technical University of Munich. In addition, we registered the trial at the ClinicalTrials.gov database (ID: NCT01574755).

Clinical and Endoscopic Evaluation

The overall follow-up time-frame was defined as the period between performance of APC therapy and the current follow-up interview. To evaluate the long-term success of APC therapy from the perspective of the patients, questionnaires containing the yes/no question 'Did you benefit from the procedure generally?' were given to them. The patients also assessed the extent of the discomfort at the current time by filling in a visual analogue scale (VAS) with scores ranging from 0 for 'no' to 10 for 'unbearable' symp-

Table 1. Clinical outcome of APC therapy in the long term

		p value
Patients	31	
Age, years	47 (22–70)	
Gender (male/female)	18 (58)/13 (42)	
Follow-up, months	27 (6–83)	
Benefitted	23 (74)	
VAS score (before APC)	7.6 (4.4–10.0)	
VAS score (after APC)	3.3 (0.0–10.0)	
VAS score (current follow-up)	4.0 (0.0–7.8)	
ΔVAS score (follow-up period)	–3.7 (–10.0 to 2.1)	<0.001
ΔVAS score (peri-interventional period)	–3.2 (–10.0 to 0.0)	<0.001
ΔVAS score (postinterventional period)	0.0 (–5.5 to 7.6)	0.593

Values represent medians (range: minimum–maximum) or n (%).

toms. We also asked for the extent of discomfort at the time before and shortly after APC therapy in a retrospective manner using the same VAS. Thus, we gained information about the subjective degree of globus sensation symptoms at three points. In order to evaluate the change of symptoms over time we determined the change of VAS scores (ΔVAS) between the three different dates. The first ΔVAS represents the change of VAS scores at the dates before and after APC therapy ('peri-interventional period'). The second ΔVAS represents the change of VAS scores after APC therapy up to the current questioning ('postinterventional period'). In addition, current VAS scores were also compared to those prior to APC therapy ('follow-up period'). The latter VAS score change served as the primary outcome measure. All upper endoscopic procedures were performed as outpatient examinations using Olympus endoscopes (GIF-Q180 series), additionally applying the NBI mode. To prove residual or recurrent GIP, biopsies were taken from all suspicious areas.

Statistical Analysis

Statistical analyses were conducted using R 2.13.2 (R Foundation for Statistical Computing) and IBM SPSS Statistics 20. Data are presented as medians (range: minimum–maximum) or absolute and relative frequencies. Between-group comparisons of continuous variables were performed by exact Mann-Whitney U tests using the coin package in R. Categorical variables were analyzed using Fisher's exact tests. Exact Wilcoxon signed-rank tests were calculated for VAS score changes. All reported p values are two-sided, with a significance level of 0.05, and have not been adjusted for multiple testing.

Results

Database query resulted in 188 patients who underwent upper endoscopy for the reason of globus sensation. Seventy-five patients (40%) who suffered from globus sensation revealed inlet patches. Out of this subgroup, 65% received APC of the CIP (fig. 1). The median follow-up period was 27 months (range: 6–83), and 23 of the 31 (74%) patients indicated that they benefitted from the initial APC therapy of the CIP. The median extent of globus sensation (assessed by VAS score) at the time before initial APC therapy was 7.6. The median value was 3.3 when asked about the extent at the time shortly after APC therapy and 4.0 at the time of the follow-up. The decline in symptoms (ΔVAS) was significant concerning both the peri-interventional and the overall follow-up period. The response to therapy did not differ with regard to gender [benefited: female 69% (9/13), male 78% (14/18), p = 0.689] or age [benefited: 67 years (range: 26–79), not benefited: 47 years (range: 23–79), p = 0.444]. Table 1 summarizes patient characteristics and clinical outcome.

Follow-up endoscopy of the upper gastrointestinal tract was performed in 22 patients. Neither strictures of the cervical esophagus nor any other complications attributed to APC therapy were found. Macroscopic recurrent CIP was detected in 11 of 22 cases. In 5 of these 11 cases no endoscopic control was performed after prior APC therapy. Therefore, residual CIP cannot be excluded in those patients. In no case did recurrent patches reach their original size.

Histological analysis of the endoscopically identified and biopsied CIP proved heterotopic gastric mucosa in 8 of 11 patients. They were classified as mixed type in 4 of 8 patients, oxyntic in 2 of 8 and mucoid in 2 of 8. The biopsies of the 3 (out of 11) patients without histological proof of gastric mucosa were regarded as sampling errors due to the typical endoscopic presentation of the CIP in the NBI mode.

The median follow-up interval between the endoscopic examinations was 42 months in the recurrence group and 19 months in the nonrecurrence group. All patients in the recurrence group indicated that they benefitted from the initial APC therapy. VAS scores (median value) decreased significantly from 7.6 to 1.1 directly after APC therapy (p = 0.002). The median VAS score at the current follow-up date was 4.4 in the recurrence group and therefore slightly, but not significantly, lower than for patients without recurrent/residual CIP (median VAS score: 1.1, p = 0.126). The median decrease of the VAS score in patients with recurrences was 6.7 when considering the peri-interventional period. This improvement was significantly stronger compared to patients without recurrent CIP (median: –2.4, p = 0.024). On the other hand, we noted a stronger increase of symptoms in the postinterventional period for patients with recurrence compared

Table 2. Clinical outcome of APC therapy according to endoscopic findings

	Recurrent CIP	No recurrent CIP	p value
Age, years	54 (23–79)	47 (26–78)	0.784[a]
Gender, male/female	6 (55)/5 (45)	7 (64)/4 (36)	1.000[a]
Follow-up, month	42 (11–83)	19 (11–46)	0.056[a]
Benefitted	11 (100)	8 (73)	0.214[b]
VAS score (before APC)	7.6 (6.0–10.0)	6.6 (4.0–10.0)	0.072[a]
VAS score (after APC)	1.1 (0.0–7.6)	3.0 (0.0–7.6)	0.069[a]
VAS score (current follow-up)	4.4 (0.0–7.6)	1.1 (0.0–7.6)	0.126[a]
ΔVAS score (follow-up period)	−4.3 (−10.0 to 0.0)	−4.6 (−10.0 to 2.1)	0.808[a]
ΔVAS score (peri-interventional period)	−6.7 (−10.0 to 0.0)	−2.4 (−8.9 to 0.0)	0.024[a]
ΔVAS score (postinterventional period)	2.0 (−1.0 to 8.0)	0.0 (−5.5 to 2.1)	<0.001[a]

Values represent medians (range: minimum–maximum) or n (%).
[a] Exact Mann-Whitney U test. [b] Fisher's exact test.

to those without recurring CIP (ΔVAS: 2.0 vs. 0.0, $p < 0.001$). The median decrease did not differ between the two groups with regard to the follow-up period (ΔVAS: −4.3 vs. −4.6, $p = 0.808$). A comparison of both groups and the respective development of symptoms are illustrated in table 2 and figure 2.

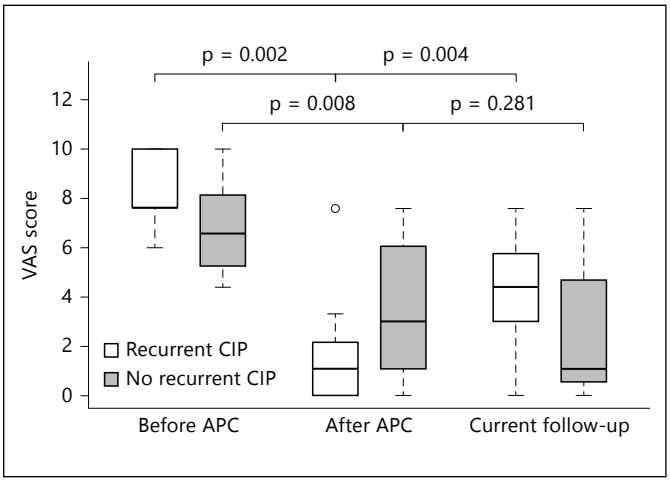

Fig. 2. The development of globus sensation symptoms for patients with and without recurrent/residual CIP. The boxplots show the median, lower and upper quartiles, and range of globus sensation symptoms measured on a VAS. White boxes refer to patients with recurrent/residual CIP, whereas gray-shaded boxes apply to patients without recurrent CIP.

Discussion

Globus sensation is a common phenomenon which occasionally causes persistent complaints and therefore compromises a patient's quality of life [5, 20, 21]. Dealing with this disease is difficult for both patients and health professionals because of the lack of a distinct structural or functional correlate. Therefore, no standardized procedure has been established in diagnostic features and treatment of globus sensation. Some authors have emphasized that reflux disease may result in atypical symptoms including globus feelings and therefore advocate a trial of PPI therapy prior to further investigations [22]. In this context it is worth noting that atypical reflux symptoms do not seem to respond to PPI therapy as well as typical reflux symptoms do [23]. However, it has been shown that the presence of CIP represent an independent risk factor for the development of globus sensation [7]. Our investigation could confirm this finding. A notable proportion of globus sensation patients (40%) actually had inlet patches which exceeded the prevalence of CIP in nonselected groups (11%) [14]. Out of this subgroup, a majority of two thirds was actually treated by APC. At least this therapy seems to be practicable. What about the effectiveness? Recent studies have demonstrated a convincing symptom relief derived from endoscopic ablation of CIP in the short term [10, 19], but data is lacking regarding the long-term outcome. Here we aimed to evaluate the long-term efficiency of this treatment.

Several limitations of our study have to be mentioned. The results of our analysis are based on a retrospective assessment of symptoms. Hence, the major drawback of

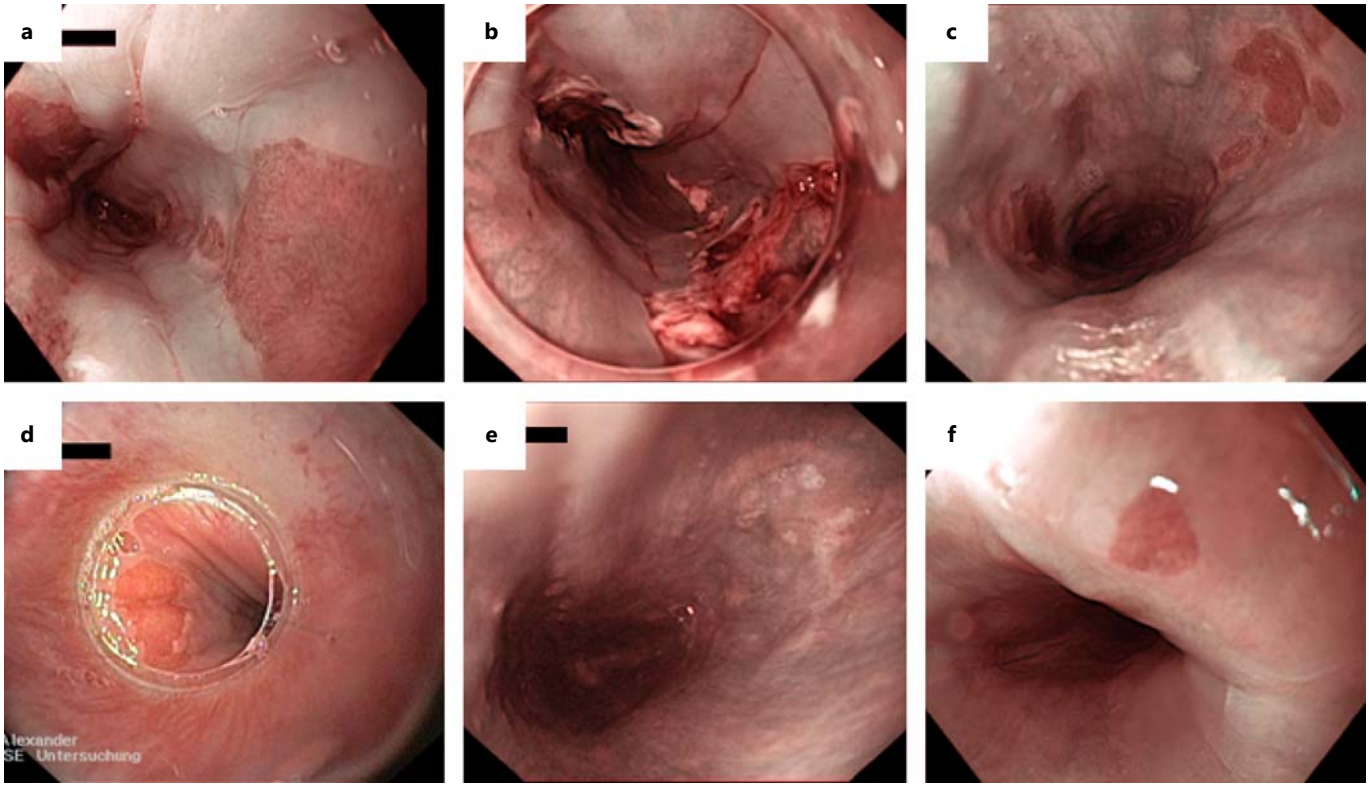

Fig. 3. Endoscopic images of the CIP course before and after treatment. In the upper row a multifocal and large CIP is shown before (**a**) and immediately after (**b**) therapy, and finally the suspected residues are demonstrated in the NBI mode (**c**). The lower row shows a comparatively small CIP APC treatment (**d**) proof of macroscopic complete eradication (**e**), and relapse (**f**).

this study design is that the symptoms that occurred a few years ago may not be remembered as accurately as the current symptoms, which may result in a biased perception. In addition, some candidates were lost to follow-up or declined to participate in follow-up endoscopy. Therefore, only a relatively small number of patients were available. Regarding the high prevalence of CIP and globus sensation patients [13, 14, 20, 24], the overall number of only 49 treated patients in an 8-year treatment period appears to be very low. Concerning this matter, prospective and controlled future studies should examine the correlation of the prevalence of CIP in globus patients.

On the other hand, we were able to achieve a significant treatment response in globus sensation patients, who are well known to be refractory to a variety of other treatment options. In this selected group of patients we surveyed a safe procedure which is generally disposable; many other therapy options like relaxation techniques, psychosomatic treatment and even antidepressants were applied in order to treat globus sensation symptoms, but all of these approaches are not recommended generally due to sparse and inconsistent data [25, 26]. In contrast, after more than 2 years of follow-up, 74% of our patients are still satisfied with the clinical result and perceive a significant reduction of symptoms. Therefore, APC therapy might be a promising option.

Surprisingly, we found a relatively high rate of recurrent CIP. Of note, in 5 patients we could not definitively prove a recurrence of CIP because these patients received no endoscopic control after the prior APC therapy. In all 5 cases the detected lesions were very small and originated from multifocal and comparatively large CIP in the past. This matter may suggest residual findings after incomplete eradication rather than recurrences. This course is illustrated in figure 3a–c.

In all other cases a complete eradication was formerly documented, but in principle microscopic residues are also possible in these patients (fig. 3d–f). Overall, we are not able to distinguish clearly between recurrences and residues on the basis of our data. Especially the fact that we do not know exactly how CIP evolve makes the inter-

pretation of our findings difficult. The recurrence of heterotopic gastric mucosa leaves an ample scope for potential pathophysiological transactions in our patients. On the one hand, buried glands after APC therapy are supposable. This matter is known from ablative endoscopic approaches in the therapy of Barrett's esophagus [27]. On the other hand, there are hints of local stem cells in CIP which might explain the recurrence [28]. This theory was underlined by another hypothesis where CIP derive from esophageal glands which lie underneath the regular squamous epithelium and somehow develop into esophageal cysts. It has been shown that cysts of the upper esophagus contain columnar epithelium producing mucin which is similar to cardiac mucosa [29]. By bursting to the surface, those cysts may uncover their columnar epithelium to the lumen of the esophagus resulting in CIP. In our study, the median follow-up time was 42 months for patients in the recurrence group and thus considerably longer than for patients in the nonrecurrence group. If new cysts would burst to the lumen at irregular and maybe long-lasting intervals, recurrences of CIP would be explainable.

Nevertheless, the clinical course of the patients with recurrence is interesting regardless of the explanation of its appearance. All of the patients assessed APC as a successful intervention and, interestingly, the initial improvement of symptoms was significantly stronger compared to recurrence-free patients measured on the basis of VAS score change. However, patients in the recurrence group also showed a remarkable reappearance of symptoms in the long term. This down and up course of symptoms in patients with recurrence might have been reinforced by the retrospective evaluation of globus sensation complaints at different time points. We have to assume that by suffering from reemerging symptoms (due to recurrent CIP) patients might assess the past effect of APC more positively. Another explanation is that inlet patches were not responsible for globus sensation symptoms in every single case. In light of the multitude of supposed causes of globus feelings, we should not disregard this possibility. But at least our data confirm the assumption that inlet patches represent one possible cause of globus sensation symptoms. Similarly, it may be reasonable to believe that recurrent globus sensation symptoms indicate a recurrence of CIP after ablation. Further prospective studies with more patients are required to confirm this latter thesis. Based on the current data we would recommend performing upper gastrointestinal endoscopy as soon as globus sensation patients report a worsening of symptoms after APC therapy.

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