TECHNOLOGY STATUS EVALUATION REPORT

The argon plasma coagulator

FEBRUARY 2002

INTRODUCTION

In order to promote the appropriate use of new or emerging technologies, the ASGE Technology Committee has developed a series of status evaluation papers. This process may present relevant information about these technologies to practicing physicians for the education and care of their patients. In many cases, data from randomized controlled trials are lacking and only preliminary clinical studies are available. Practitioners should continue to monitor the medical literature for subsequent data about the efficacy, safety, and social economic aspects of the technologies.

BACKGROUND

The Argon Plasma Coagulator (APC) is a device intended for thermal coagulation of tissue. Having been introduced in open and laparoscopic surgery, APC was adapted for use in flexible endoscopy in 1991 and has many potential uses.[1] Delivered through a flexible probe passed through the accessory channel, it is noncontact and may allow treatment of a large surface area quickly. Its principles of action are sufficiently different from other thermal coagulation devices such as to warrant this report.

TECHNOLOGY UNDER REVIEW

Physical principles

APC is a noncontact electrocoagulation device that uses high-frequency monopolar current conducted to target tissues through ionized argon gas (argon plasma). Electrons flow through a channel of electrically activated, ionized argon gas from the probe electrode to the targeted tissue. Current density on arrival at the tissue surface causes coagulation. Coagulation depth is dependent on generator power setting, flow rate of the argon gas, duration of application, and distance of the probe tip to the target tissue.[2] The argon arc contacts tissue closest to the electrode allowing for en face or tangential coagulation. With thermal coagulation of tissue, a thin, superficial, electrically insulating zone of desiccation and a steam layer (from the boiling of tissue) result, both contributing to limit carbonization and depth of coagulation[1] The insulating zone of desiccation produces increased electrical resistance in the treated area. This prompts the current to move to another point on the tissue surface where resistance is lower.[1-5] However, with prolonged application carbonization, vaporization, and deep tissue injury can occur.

EQUIPMENT

The APC apparatus includes a high-frequency monopolar electrosurgical generator, source of argon gas, gas flow meter, flexible delivery catheters, grounding pad, and foot switch to activate both gas and energy. Probes are available that direct the plasma parallel or perpendicular to the axis of the catheter. APC systems (ERBE Elektromedizin, Tübingen, Germany; and Conmed, Utica, N.Y.) include an electrosurgical unit that generates a high frequency electrical current, an argon gas cylinder, and a gas flow meter. Disposable probes for endoscopic application consists of a flexible teflon tube with a tungsten monopolar electrode contained in a ceramic nozzle located close to its distal end. APC probes are available in a variety of diameters and lengths (2.3 mm OD [220 cm, and 440 cm length], and 3.2 mm OD [220 cm length]). A foot switch synchronizes argon gas release with the delivery of electrical current. Generators deliver an output voltage of 5000-6500 V; the power can be adjusted between 0 and 155 W. The argon gas flow may be adjusted from 0.5 L/mn to 7 L/mn.

TECHNIQUE

The device settings used have varied by manufacturer, indications, and study protocols. In vitro APC experiments demonstrated that depth and diameter of the coagulation zone increased with duration of application and increase in power settings.[2,4] In general, low power and low argon flow rates are used for hemostasis of superficial vascular lesions with settings of 40 to 50 W and 0.8 L/mn. Higher output settings are used for the tissue ablation with settings up to 70 to 90 W and 1 L/mn.[3] Very high flow rates may result in prompt gaseous distention and patient discomfort.

The operative distance between probe and tissue ranges from 2 to 8 mm.[6] At low power settings, the probe tip must be close to the tissue to allow the argon plasma to contact the targeted tissue. The surface of the targeted tissue should be free of liquid (including blood). If the surface is not clear, a coagulated film develops leaving the tissue surface beneath inadequately treated. This limits use in active hemorrhage. Surface fluids should be cleared by washing and suctioning as necessary.

APC is performed with applications of 0.5 to 2 second duration.[7] The probe tip can be directed to "paint" confluent or near-confluent surface areas. A 2-channel endoscope allows concomitant aspiration of the argon gas. Tissue contact with the probe tip should be avoided. When the tip makes tissue contact it functions as a contact monopolar probe. Deep thermal injury will allow argon gas to flow into the submucosa producing pneumatosis and even extraintestinal gas. The dissected gas usually resorbes rapidly. However, this complication may produce symptoms and is apt to compromise the completeness of the treatment session.[3] Care should be taken to avoid misdirection the plasma jet to the endoscope tip that could result in damage to the video chip. When treating tissue in contact with metal implants such as stents, current and/or power settings should be decreased accordingly.

INDICATIONS AND EFFICACY

The uses of the APC can be broadly categorized as hemostatic or ablative.

HEMOSTASIS

Vascular Ectasias. The APC has been used successfully to treat vascular ectasia of the upper and lower digestive tract including gastric antral vascular ectasia syndrome (GAVE), sporadic angiodysplasia, hemorrhagic telangiectasia, and radiation-induced enteropathy and proctopathy.[4,8-12]

In one study, 17 patients with GAVE were treated successfully with APC, achieving eradication in 1 to 4 treatment sessions.[13] Over a mean follow-up of 30.4 months, recurrent GAVE occurred in 5 patients requiring further treatment.

Five retrospective studies evaluated 78 patients with radiation proctopathy treated with APC.[11,14-17] Using various definitions of success, all but 5 patients (94%) improved after treatment with 8 to 28 months' follow-up. Recurrence of significant bleeding was reported in 3 patients. Three patients experienced self-limited anorectal pain after treatment, 2 developed chronic rectal ulcers, and 2 developed strictures requiring rectal dilatation.

Bleeding ulcers. Treatment of ulcer bleeding with APC has been reported, included in larger series addressing a variety of lesions.[7,18] A small, (n = 41) randomized trial, with limited statistical power, comparing APC to heater probe for endoscopic hemostasis of bleeding ulcers (visible vessel or actively bleeding lesions) showed no difference in outcomes.[19] As a noncontact mode of therapy, APC does not incorporate coaptive pressure.

Bleeding varices. Thirty patients were randomized to endoscopic ligation of esophageal varices with or without APC (used to further achieve mucosal fibrosis once the varices had become small). Although the combined therapy group experienced a higher incidence of pyrexia, its cumulative recurrence-free rate at 24 months was significantly lower than for the ligation only group (74% vs. 50%, $p < 0.05$).[6]

ABLATION

Barrett's esophagus. A number of case series report the use of APC in treating patients with varying lengths of Barrett's esophagus including patients with low-grade dysplasia and in situ adenocarcinoma.[20-28] In most cases, patients also received high-dose proton-pump inhibition; some also received sucralfate, whereas others underwent subsequent antireflux surgery. Combining selected studies, after a mean of 2.5 treatment sessions, using various methods of confirmation of success, ablation was noted in 68% of the 91 patients with 6 to 36 months follow-up.[20,22,24,25] A better result was noted in patients with shorter, noncircumferential extensions of Barrett's.[22] Overall, results vary greatly: in one study, squamous regeneration was noted in 69 of 70 patients with no evidence of relapse over a median of 12 months, whereas in another, only 17 of 30 patients achieved this result with a median follow-up of 9 months.[26,27]

Complications have been noted: in one study, 58% of patients developed moderate to severe chest pain and odynophagia within 3 to 10 days after the procedure whereas 5 developed high fevers and pleural effusions.[25] In 3 studies totaling 177 patients, 1 patient developed diffuse severe esophagitis, requiring transfusions and 8 others (4.5%) required dilatation for esophageal strictures.[22,25,29] In one study, 2 of 27 patients who completed treatment had a perforation with one death, early in the study.[27] Pneumomediastinum and subcutaneous emphysema without obvious perforation have also been reported. Most significantly, a case of intramucosal adenocarcinoma diagnosed 18 months after apparent complete squamous re-epithelialization achieved with APC in a patient presenting initially with Barrett's esophagus without dysplasia has been reported.[30] Ablative therapy for Barrett's esophagus remains investigational at this time.

Polyps and Remnant Adenomatous Tissue After Polypectomy. Two case series describe the use of APC for ablation of intestinal polyps as well as for ablation of residual adenomatous tissue after gastric and colonic polypectomy.[4,8] The utility of APC for the eradication of postpolypectomy residual adenomatous tissue was described in a subsequent larger series. Of 30 patients with residual adenomatous tissue after endoscopic polypectomy, 15 had complete eradication after one APC session and all had complete eradication after two sessions.[31]

Debulking Malignant Tumors. The largest study of APC for inoperable cancer of the esophagus or cardia reports on 83 patients treated with recanalization enabling passage of normal food in 48 (58%) after 1 session, and 22 (26%) after 2 sessions.[32] In the remaining patients, the dysphagia score improved by at least one grade. Perforation occurred in 7 (8.3%) patients, with all but one being treated conservatively.

The APC has been used in small series to treat tumors of the ampulla of Vater, and nonsuperficial colonic tumors.[4,8] The APC was also used for nonoperative candidates with endosonographic and histologic T1 tumors of the esophagus, stomach, and rectum. The treatment achieved complete local response in 9 of 10 patients over a 9.5-month follow-up.[33]

Miscellaneous. APC has also been used to ablate dysplastic heterotopic mucosa, to recanalize occluded or overgrown metal stents or cut displaced metal stents.[7,26,34-37] One group has reported on its extensive experience at treating patients with Zenker's diverticulum endoscopically.[8,38] In the hands of these authors, the APC is a very useful effective tool for this indication (125 patients, mean number of sessions 1.8), although a number of patients were also treated with additional endoscopic methods.

SAFETY

As APC is applied in monopolar mode, all the safety principles of monopolar high-frequency electrosurgical procedures apply, including the placement of a grounding-pad electrode. Differences in adopted study methodologies, operator experience, heterogeneous indications and patient populations, variable follow-up, disparate definitions of complications, and probable publication bias all limit the interpretation of safety data in the published experience to date. Reported complication rates range from 0% to 24% and include gaseous distention, pneumatosis intestinalis, pneumoperitoneum, pneumomediastinum, subcutaneous emphasema, pain at the treatment site, chronic ulceration, stricture, bleeding, transmural burn syndrome, perforation, and death.

FINANCIAL CONSIDERATIONS

As a noncontact thermal device, its applications overlap with those of endoscopic laser therapy. When compared with a laser, the APC is more compact, mobile, and versatile, and is less costly. When compared with contact thermal probes, the APC system is more complex and the APC probes are more costly. However, the APC generator may be used with other monopolar and multipolar thermal devices. The list prices of the Erbe APC 300 Plasma Coagulator system, including the ICC 200 E/A generator and argon gas cylinder, and the Conmed System 7500 ABC are both approximately $24,500. The unit cost of APC disposable probes is $189.[39] CPT codes are based on the procedure performed with no accounting for the specific device used.

COST-EFFECTIVENESS

No formal cost-effectiveness studies have been published to date.

SUMMARY

The APC is a method of noncontact endoscopic thermal coagulation. The majority of the published experience is non-randomized and retrospective. The limited published data indicate that, with attention to technique and at recommended settings, APC can be used safely for gastrointestinal endoscopic applications. It appears to be best suited for hemostasis of diffuse superficial vascular lesions such as gastric antral vascular ectasia syndrome and radiation induced proctopathy. However, there are insufficient comparative data to assess its performance relative to other modalities including cost-effectiveness analyses. Similarly there is limited published experience of APC for ablation therapy. The role of APC for hemostasis and ablative therapies requires further study.

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