Medtronic

РАДИОЧАСТОТНАЯ АБЛЯЦИЯ BARRX

В ЛЕЧЕНИИ ЛУЧЕВОГО (РАДИАЦИОННОГО) ПРОКТИТА

АННА ПРОНИНА
Medtronic
2021

ГЕНЕРАТОР ДЛЯ РАДИОЧАСТОТНОЙ АБЛЯЦИИ BARRX - ПРЕДНАЗНАЧЕНИЕ

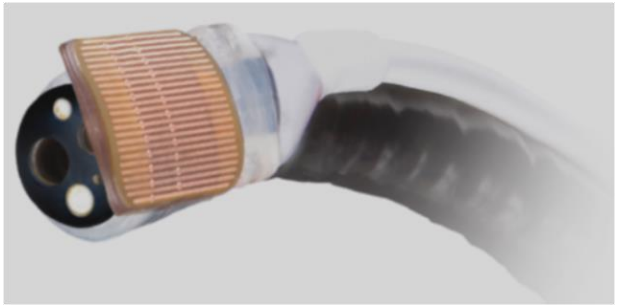
Радиочастотная абляция одобрена FDA в следующем применении:

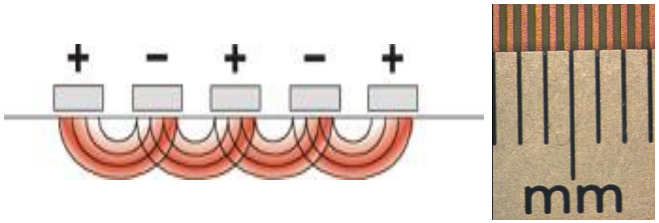
Фокальные катетеры Barrx™ «...предназначены для использованияпри коагуляции кровоточащих и не кровоточащих участков желудочно-кишечного тракта включая, но не ограничиваясь пищеводом»

Основные показания: пищевод Барретта, лучевой проктит.

12. Instructions For Use. Specific to the use of the Barrx™ Focal Catheters for the sub-indication of bleeding and non-bleeding sites in the gastrointestinal tract . Covidien, 15 Hampshire St., Mansfield, MA 02048. Part No.1062395 717-0051-01 and 717-0056-01.

ГЕНЕРАТОР ДЛЯ РАДИОЧАСТОТНОЙ АБЛЯЦИИ BARRX



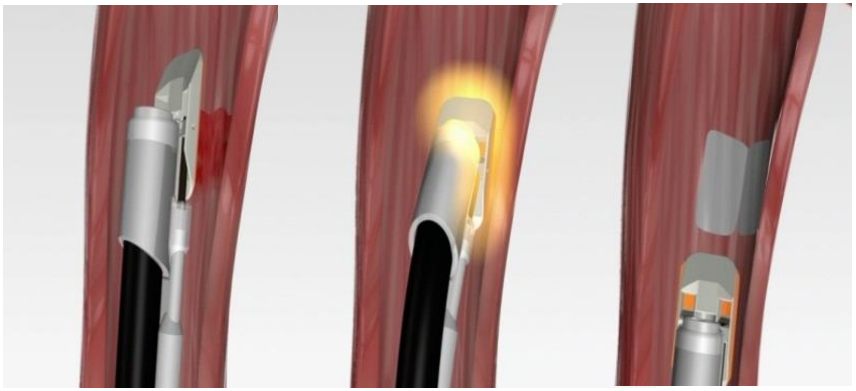


Механизм работы

1. Близко расположенные друг к другу электроды – биполярный тип электрохирургии, исключена необходимость в плате пациента
2. Генератор контролирует процесс перестает подавать энергию (10-12 Дж/см^2) через катетер, когда предопределенный уровень ответа в обрабатываемом участке достигнут

BARRX™ 90 ФОКАЛЬНЫЙ КАТЕТЕР

- Код инструмента: «90-9100»
- 1.3см ширина x 2.0 см длина
- Наиболее часто используемый тип катетера, подходит для большинства процедур
- Монтируется на дистальный конец эндоскопа, позволяет осуществлять эндоскопический обзор во время процедуры



ЛУЧЕВОЙ (РАДИАЦИОННЫЙ) ПРОКТИТ

- Пациенты могут иметь ректальное кровотечение и анемию
- Другие симптомы: диарея, частые позывы, боли в прямой кишке, тенезмы, недержание кала[7]
- Чаще всего в качестве первой линии терапии применяется АПК. Однако, могут возникать осложнения, включая не вылеченные изъязвления, диарею, боль, свищи и ректальный стеноз[7,9,10,11]
- Имеются благоприятные данные о проведении РЧА при данной патологии. К преимуществам относят поверхностный характер абляции при возможности обработки обширных участков, а также последующую надежную эпителизацию[11]

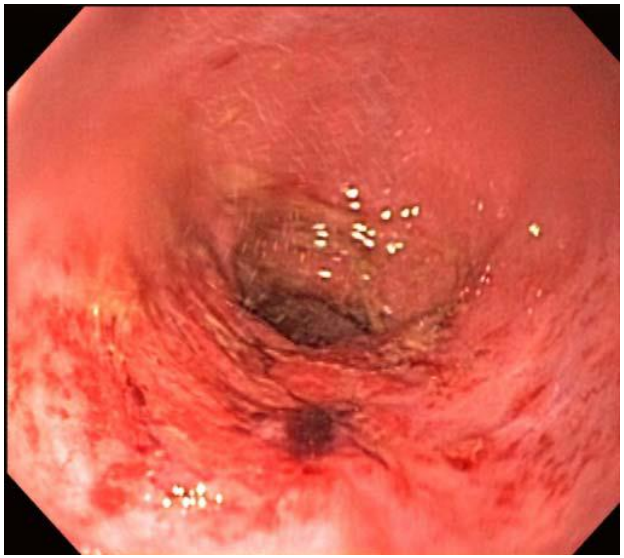
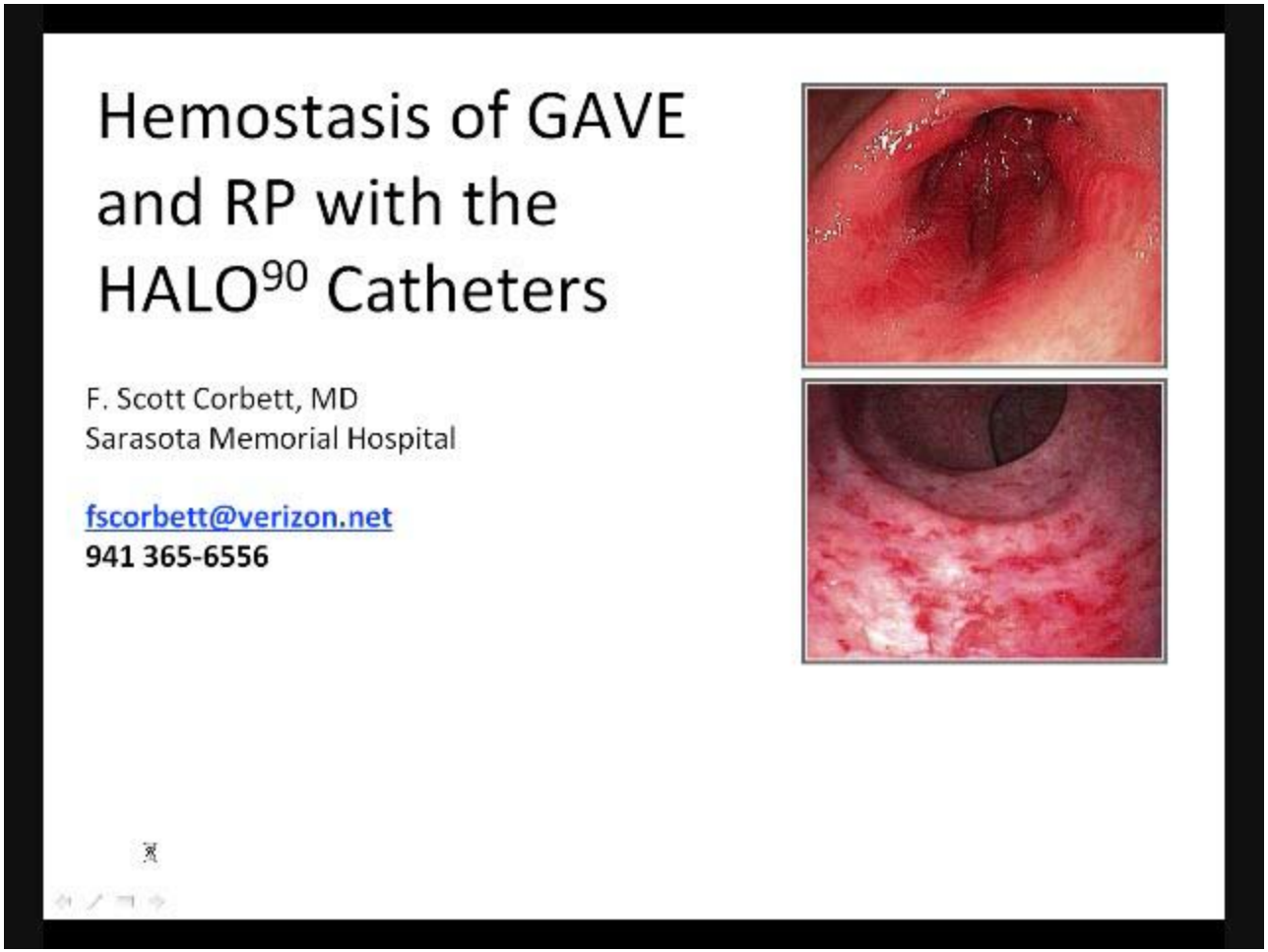


Image courtesy of Jose Nieto, DO, Borland-Groover Clinic, Jacksonville, FL

7. Rustagi T, Corbett FS, Mashimo H. Treatment of chronic radiation proctopathy with radiofrequency ablation (with video). *Gastrointestinal Endoscopy* 2014; pii: S0016-5107(14)01406-0. doi: 10.1016/j.gie.2014.04.038. [Epub ahead of print].
9. Villavicencio RT, Rex DK, Rahmani E. Efficacy and complications of argon plasma coagulation for hematochezia related to radiation proctopathy. *Gastrointest Endosc*. 2002;55:70-74.
10. Rotondano G, Bianco MA, Marmo R, Piscopo R, Cipolletta L. Long-term outcome of argon plasma coagulation therapy for bleeding caused by chronic radiation proctopathy. *Dig Liver Dis*. 2003;35:806-810.
11. Shahbaz O, Tadros M, Chaletsky DM. Radiofrequency ablation for the management of radiation proctitis: an effective and safe treatment modality. *Gastrointestinal Endoscopy* 2014; 79(5): 566-567.

ТЕРАПИЯ РАДИАЦИОННОГО ПРОКТИТА ПРИ ПОМОЩИ ТЕХНОЛОГИИ BARRX
DR. SCOTT CORBETT, SARASOTA MEMORIAL HOSPITAL



ПОТЕНЦИАЛЬНЫЕ ПРЕИМУЩЕСТВА РЧА В ТЕРАПИИ ПАЦИЕНТОВ С РАДИАЦИОННЫМ ПРОКТИТОМ

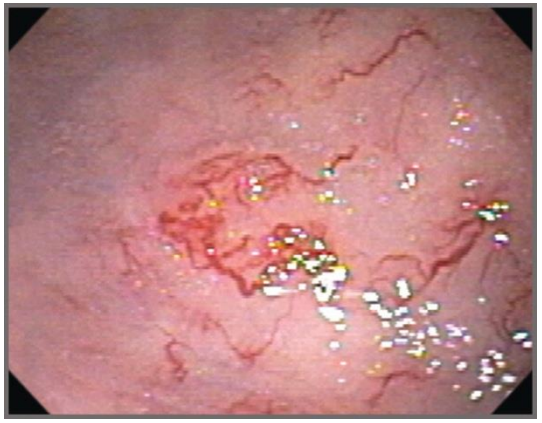
- Возможность абляции большой по площади поверхности[11]
- Контролируемая, равномерная и поверхностная абляция [5,11,13,16]
- Надежная эпителизация после процедуры[11]

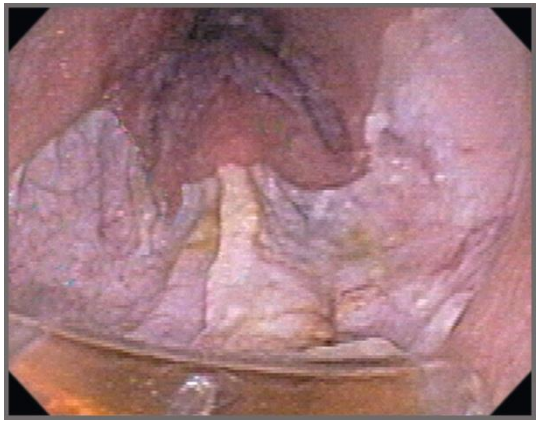
Comparison of tissue ablation areas using Barrx™ Ultra Long RFA Focal Catheter, Barrx™ 90 RFA Focal Catheter, Barrx™ Channel RFA Endoscopic Catheter and APC

5.Dray X, Repici A, Pedro Gonzalez P, et al. Radiofrequency ablation for the treatment of gastric antral vascular ectasia. *Endoscopy* 2014.08 [Epub ahead of print].
11.Shahbaz O, Tadros M, Chaletsky DM. Radiofrequency ablation for the management of radiation proctitis: an effective and safe treatment modality. *Gastrointestinal Endoscopy* 2014; 79(5): 566-567.
13.McGorisk T, Krishnan K, Keefer L, Komanduri S. Radiofrequency ablation for refractory gastric antral vascular ectasia (with video). *Gastrointest Endosc* 2013; 78(4): 584-8.
16. Dray X, Battaglia G, Wengrower D, et al. Radiofrequency ablation for the treatment of radiation proctitis. Endoscopy 2014; 46:970-6.

РЧА ПРИ РАДИАЦИОННОМ ПРОКТИТЕ

- **Title**: RFA for the Management of Radiation Proctitis: an Effective and Safe Treatment Modality[11]
- **Authors**: Shahbaz O, Tadros M, Chaletsky DM
- **Journal**: Gastrointestinal Endoscopy, 2014
- **Number of patients**: 10
- **Patient Characteristics**:
  - All had rectal bleeding secondary to radiation proctopathy
  - 6 had failed other therapies, 2 were transfusion dependent
- **Methods:**
  - At least 1 RFA session
  - Primary outcomes: resolution of bleeding, stabilization of hemoglobin
- **Results:**
  - 9 had resolution of bleeding and the majority had improved hemoglobin
  - 7 required 1 RFA session, 2 required 2 RFA sessions
  - 1 failed after 5 sessions
- **Adverse events**: None





Images courtesy of F. Scott Corbett, MD, Sarasota Memorial Hospital, Florida Digestive Health Specialists, FL

11.Shahbaz O, Tadros M, Chaletsky DM. Radiofrequency ablation for the management of radiation proctitis: an effective and safe treatment modality. *Gastrointestinal Endoscopy* 2014; 79(5): 566-567.

РЧА ПРИ РАДИАЦИОННОМ ПРОКТИТЕ

- **Title**: Treatment of chronic radiation proctopathy with RFA (with video)[7]
- **Authors**: Rustagi T, Corbett FS, Mashimo H
- **Journal**: Gastrointestinal Endoscopy, August 2014
- **Number of patients**: 39
- **Patient Characteristics**:
  - History of pelvic radiation treatment > 6 months prior
  - Recurrent hematochezia for > 3 months with endoscopic evidence of RP
- **Type of device used**: Barrx™ 90
- **Treatment method**:
  - Generally 2 pulses/site
  - Ablations placed approximately 1 mm proximal to dentate line
  - Restricted treatments to lengths ≤ 6 cm/session, and <270°/session
- **Outcomes**:
  - Mean # RFA sessions: 1.5
  - Mean follow-up: 28 months post-treatment (range 7-53 mo)
  - Mean time between sessions: 18.1 weeks
  - Complete cessation of visible bleeding in all patients
  - Overall 14% improvement in mean Hgb; 11.8 gm % → 13.5 gm %
  - Discontinuation of blood transfusion in 11/12 (92%)

ORIGINAL ARTICLE

Treatment of chronic radiation proctopathy with radiofrequency ablation (with video)

Tarun Rustagi, MD,[1] F. Scott Corbett, MD,[2] Hiroshi Mashimo, MD, PhD[3]

New Haven, Connecticut; Sarasota, Florida; Boston, Massachusetts, USA

Background: Chronic radiation proctopathy (CRP) is a common sequela occurring even many years after pelvic radiation. Current ablative therapies for bleeding ectatic vessels have the potential for deep tissue injury leading to ulcerations, perforation, and fistulas. Radiofrequency ablation (RFA) therapy avoids deep tissue injury and is a promising treatment for CRP.

Objective: To assess the long-term safety and efficacy of RFA for the treatment of CRP.

Design: Multicenter, retrospective analysis of a prospectively collected database.

Setting: Veterans Affairs Boston Healthcare System, Massachusetts; Sarasota Memorial Hospital and Suncoast Endoscopy of Sarasota, Florida.

Patients: A total of 39 consecutive patients with CRP.

Interventions: Endoscopic RFA of CRP.

Main Outcome Measurements: The primary endpoint of the study was complete resolution of rectal bleeding. Secondary endpoints included visually scored improvement of CRP on endoscopic follow-up by using a rectal telangiectasia density (RTD) grading score, improvement in hemoglobin level, and adverse events related to the procedure.

Results: A total of 39 male patients (mean [± standard deviation {SD}] age 72.9 ± 6.6 years) were included in the study. The mean number of RFA sessions was 1.49 (median 1, interquartile range [IQR] 1-2, range 1-4), with a mean interval of 18 weeks between sessions. Rectal bleeding stopped completely in all patients during the mean follow-up of 28 months (range 7-53 months). A significant improvement occurred in the mean (± SD) hemoglobin level from 11.8 ± 2 to 13.5 ± 1.6 g % ($P < .0001$). Endoscopic severity also improved significantly with an improvement in the median RTD score from 3 (IQR 2-3) to 0 (IQR 0-1) ($P < .0001$). Treatment with RFA led to discontinuation of blood transfusion and iron therapy in 92% and 82% patients, respectively.

Limitations: Retrospective analysis, lack of control group.

Conclusion: RFA therapy led to complete resolution of rectal bleeding in all treated CRP patients, with improvement in clinical and endoscopic indices without any major adverse events. Further controlled studies are needed to establish RFA as the endoscopic therapy of choice for treatment of CRP. (Gastrointest Endosc 2014;■:1-9.)

Adverse events:

- Transient mild to moderate anorectal pain (12%) and transient fecal incontinence (2 patients)
- One patient had a significant but hemodynamically stable anorectal hemorrhage after deviation from suggested protocol (2 ablations of 12J/cm^2 per treatment site), treated with hemostatic clip, no need for transfusion

7. Rustagi T, Corbett FS, Mashimo H. Treatment of chronic radiation proctopathy with radiofrequency ablation (with video). *Gastrointestinal Endoscopy* 2014; pii: S0016-5107(14)01406-0. doi: 10.1016/j.gie.2014.04.038. [Epub ahead of print.

ТЕХНИКА ПРОЦЕДУРЫ

- Contraindications:
  - Pregnancy
  - Presence of gastric or colorectal ulcers
  - History of anal incontinence
  - Presence of anorectal fistulae
  - Pelvic irradiation within the last six months
- Warning:
  - Failure to discontinue platelet inhibiting and anti-thrombotic agents 7 days before and after therapy may lead to higher rates of bleeding, and the need for transfusion and/or additional intervention for hemostasis
- Most studies and case reports used the Barrx™ 90 (GAVE, RP) or Barrx™ 90 ULTRA (GAVE)
- Potential benefits of Barrx™ Channel RFA Endoscopic Catheter:
  - No repositioning of the catheter to reach target areas
  - Ease of intubation given through-the-scope catheter
  - Allows ablation within gastric folds
  - When treating RP, no need to retroflex endoscope and catheter as entire ablation zone is well visualized

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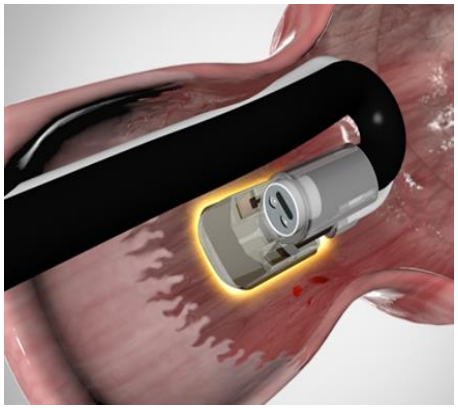
ТЕХНИКА ПРОЦЕДУРЫ

- Катетер для абляции располагают на дистальном конце эндоскопа на 12 или 6 часах
- В прямой кишке эндоскоп может быть изогнут в ретрофлексию, что позволяет при расположении катетера на 6 часах обработать необходимый участок в близости к зубчатой линии прямой кишки
- Всего требуется подача 1-2 абляций к одному участку в толстой кишке
- Коагулят, образовавшийся в ходе процедуры, не требует удаления или очистки (во избежание кровотечения, вызванного механическим воздействием)
- Катетер для абляции и эндоскоп могут быть извлечены для очистки в ходе процедуры



Катетер располагается на 6 часах, таким образом, эндоскоп может быть изогнут в ретрофлексию для обработки зубчатой линии

Очистка рабочей поверхности катетера Barrx™ 90

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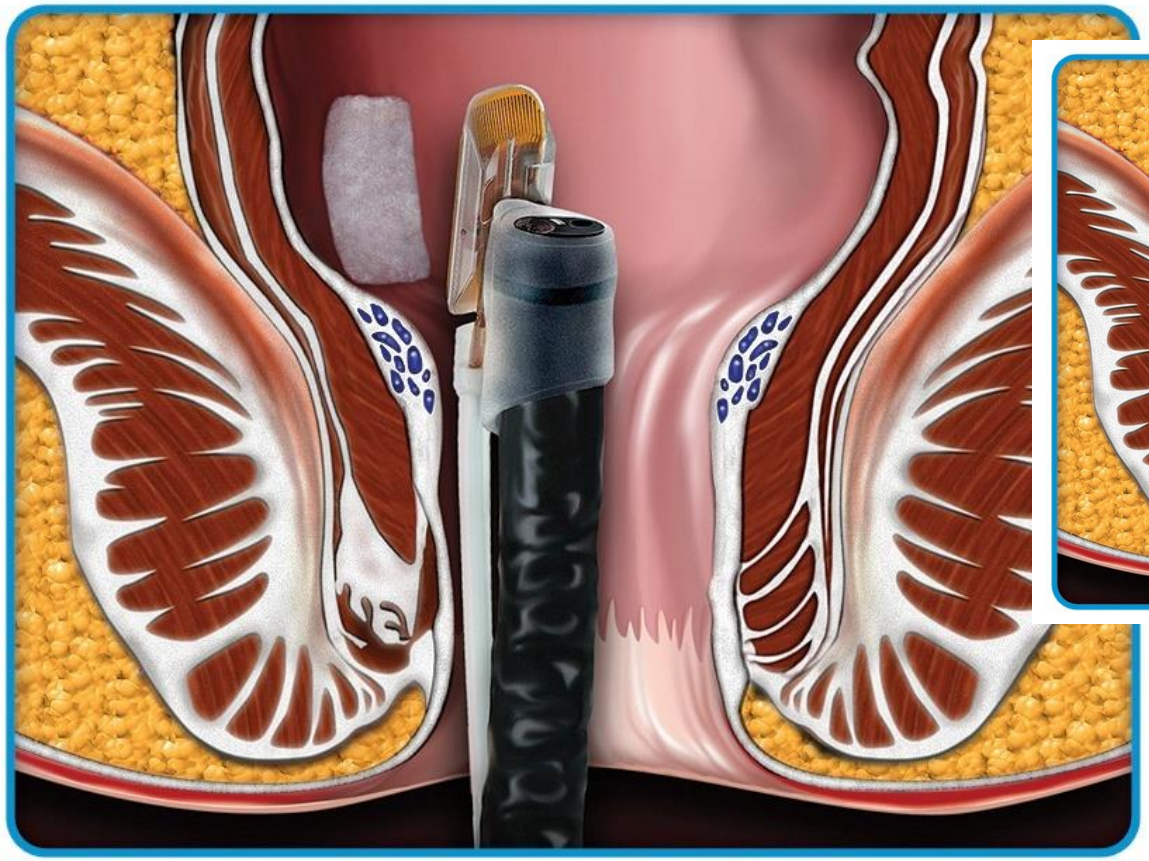
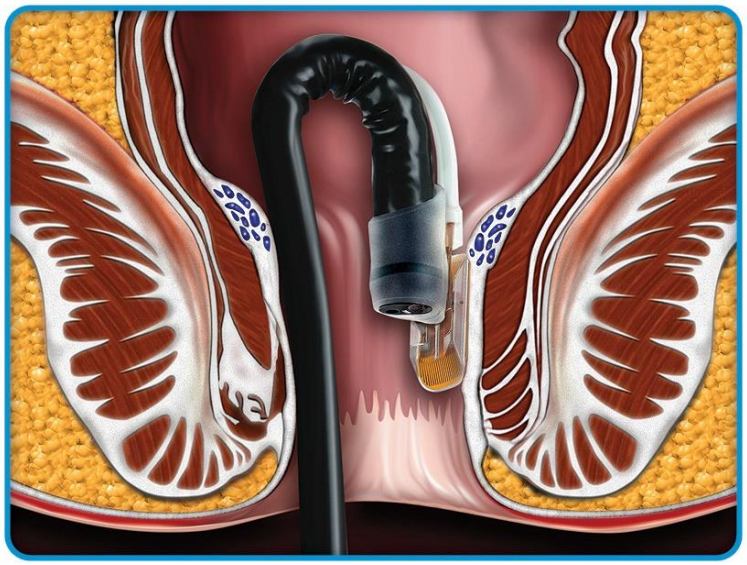
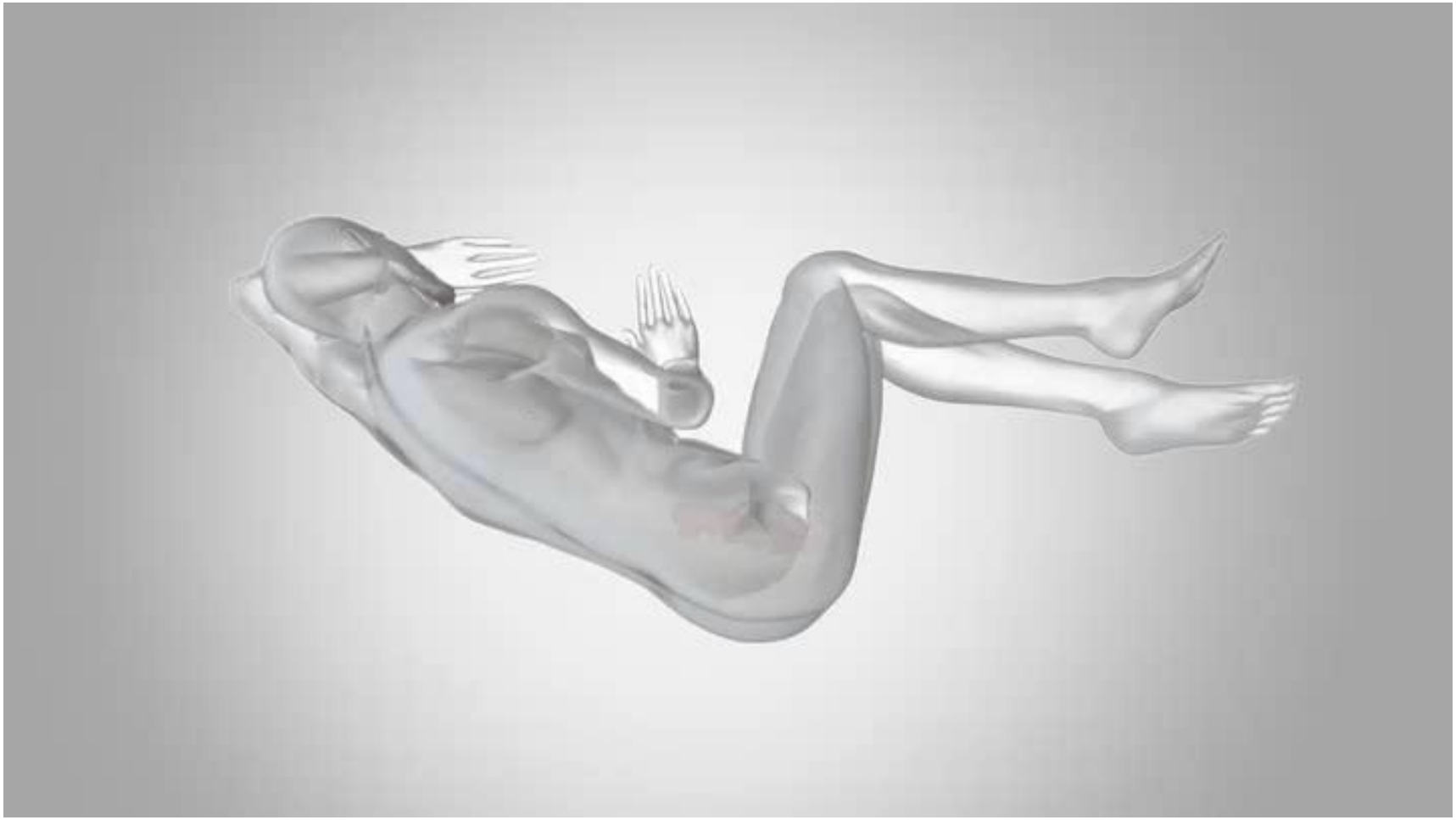
ПОЗИЦИОНИРОВАНИЕ ИНСТРУМЕНТА





ВИДЕО: ПРОЦЕДУРА ТЕРАПИИ РЧА ПРИ ЛУЧЕВОМ ПРОКТИТЕ

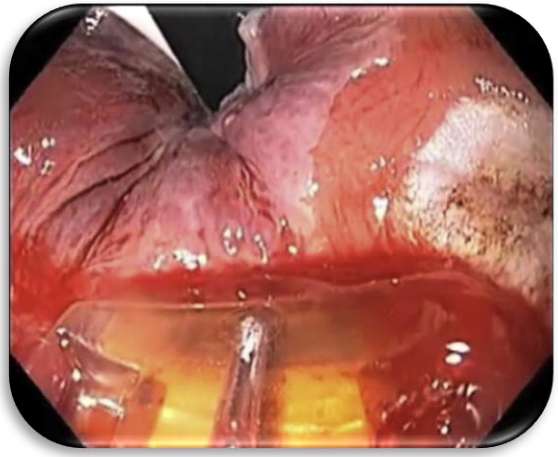


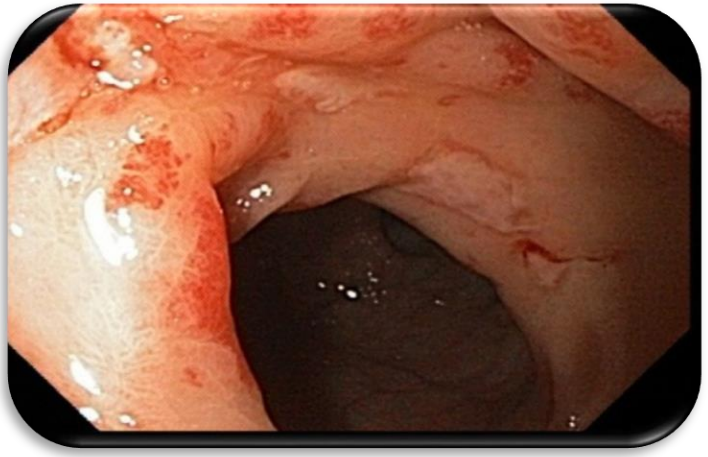
РАДИАЦИОННЫЙ ПРОКТИТ – ОДНО ИЗ ПОКАЗАНИЙ К РЧА

Radiofrequency ablation for the treatment of radiation proctitis

Authors Xavier Dray[1], Gorgio Battaglia[2], Dov Wengrower[3], Pedro Gonzalez[4], Alessandra Carlino[5], Marine Camus[1], Tomer Adar[3], Francisco Pérez-Roldán[4], Philippe Marteau[1], Alessandro Repici[5]

Institutions Institutions are listed at the end of article.





3 месяца после процедуры