



The dark side of the guidelines  
2<sup>nd</sup> Interventional Radiologist under 40 Meeting



*Interventional Oncology*

8-10 Maggio 2017

*Bologna*

*Società Medica Chirurgica - Palazzo dell'Archiginnasio*

# IL COLANGIOCARCINOMA EXTRAEPATICO INOPERABILE: BRACHITERAPIA E RF ENDODUTTALE?

*Paolo Rigamonti*

Sistema Socio Sanitario



Regione  
Lombardia

ASST Santi Paolo e Carlo

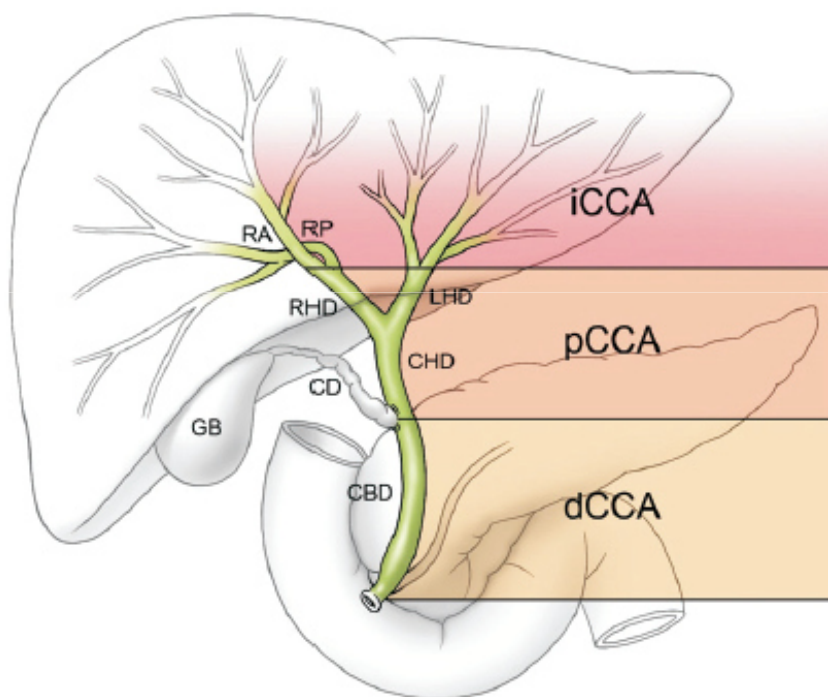


Milano - ITALY

**SAN CARLO BORROMEO** OSPEDALE



# COLANGIOCARCINOMA EXTRAEPATICO



Visual Art: © 2014 The University of Texas MD Anderson Cancer Center

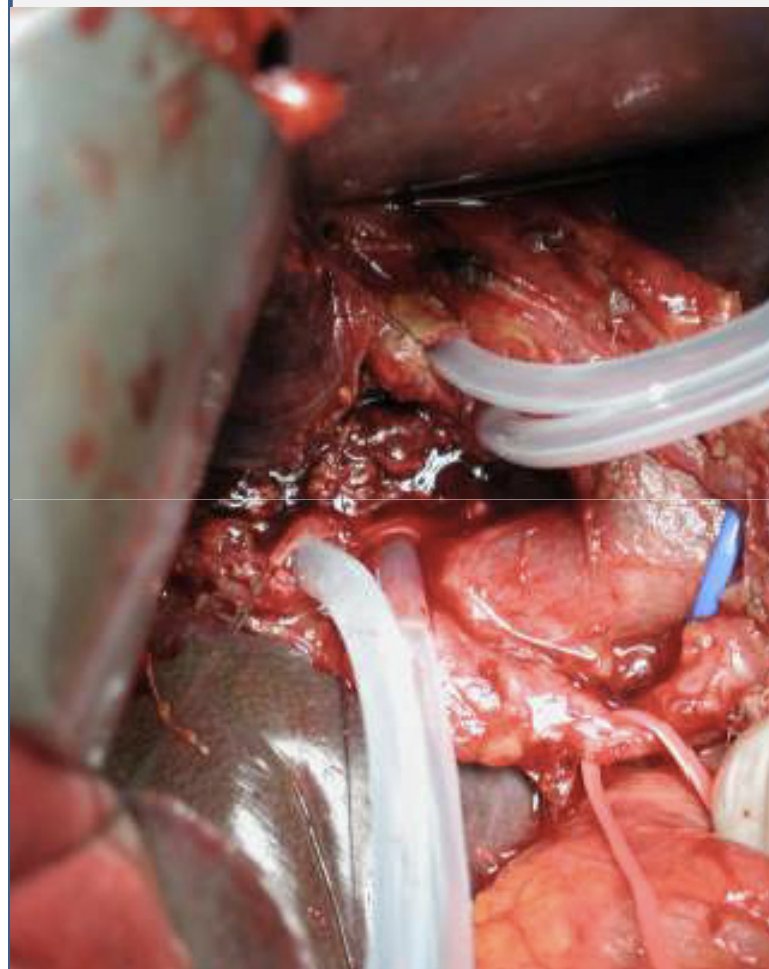
## Intraepatico

La lesione è localizzata prossimalmente alle diramazioni biliari di II ordine

## Extraepatico

**Perilare:** la lesione è localizzata oltre le diramazioni di II ordine sino a prima dell'inserzione del dotto cistico

**Distale:** lesione localizzata oltre il dotto cistico fino a prima dell'ampolla di Vater



- ▶ For perihilar CC, the Bismuth classification is a guide to the extent of surgery required (aim is tumour-free margin of >5 mm). Surgical treatment is principally as follows (Grade B):
  - For types I and II: en bloc resection of the extrahepatic bile ducts and gall bladder, regional lymphadenectomy and Roux-en-Y hepaticojejunostomy.
  - For type III: as above plus right or left hepatectomy.
  - For type IV: not usually resectable but extended right or left hepatectomy may be feasible, dependent on biliary anatomy.
- ▶ Segment 1 of the liver may preferentially harbour metastatic disease from hilar CC and removal should be considered with stages II–IV.
- ▶ Intrahepatic CCs are managed by segmental or lobe resection.
- ▶ Distal CCs are treated by pancreato-duodenectomy.
- ▶ Increasing data suggest that liver transplantation for CC can be successful in rigorously selected patients undergoing neoadjuvant therapy in highly specialised centres.



# CRITERI DI NON RESECABILITÀ

## Cholangiocarcinoma

Tushar Patel

**REVIEW**

GASTROENTEROLOGY & HEPATOLOGY

JANUARY 2006 VOL 3 NO 1

**Box 2** Selection for surgical resection—criteria for unresectability for hilar lesions.

### Vascular involvement

- Hepatic artery invasion
- Encasement or occlusion of the main portal vein proximal to the bifurcation
- Bilateral involvement of hepatic arteries

### Extent of distant spread

- Extrahepatic adjacent local invasion
- Nodal metastases beyond the hepatoduodenal ligament
- Disseminated disease

### Extent of local disease

- Bilateral involvement of hepatic ducts to the level of the secondary biliary radicals
- Atrophy of one liver lobe with encasement of the contralateral portal vein branch
- Atrophy of one liver lobe with contralateral secondary biliary radical involvement



La chirurgia è l'unico trattamento curativo per il paziente con colangiocarcinoma

Tuttavia meno di 1/3 dei paziente sono operabili al momento della diagnosi.

Il tasso di sopravvivenza a 5 anni dopo resezione è per i CC intraepatici (22-44%), distali (27-37%) e ilari (11-41%)

# IL RESTANTE 70%

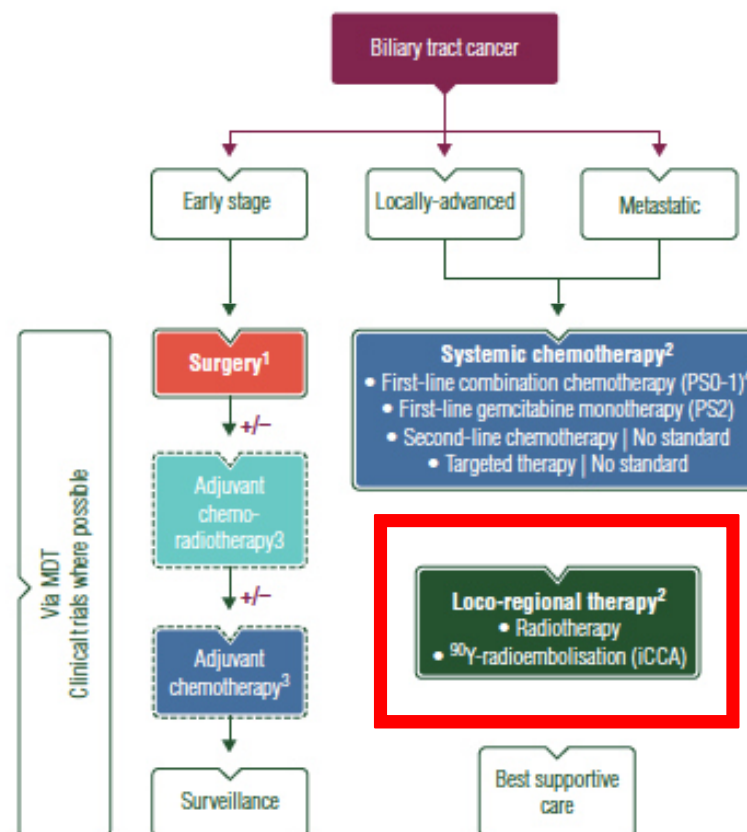
clinical practice guidelines

## Biliary cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up<sup>†</sup>

J. W. Valle<sup>1</sup>, I. Borbath<sup>2</sup>, S. A. Khan<sup>3</sup>, F. Huguet<sup>4</sup>, T. Gruenberger<sup>5</sup> & D. Arnold<sup>6</sup> On behalf of the ESMO Guidelines Committee<sup>\*</sup>

<sup>†</sup>Department of Medical Oncology, The Christie NHS Foundation Trust, Institute of Cancer Sciences, University of Manchester, Manchester, UK; <sup>2</sup>Department of Gastroenterology, Clinique Universitaire Saint-Luc, Brussels, Belgium; <sup>3</sup>Hepatology and Gastroenterology Section, Department of Medicine, Imperial College, London, UK; <sup>4</sup>Department of Radiation Oncology, Tenon Hospital, APHP, University Paris VI, Paris, France; <sup>5</sup>1st Department of Surgery, Rudolfsstiftung Hospital, Vienna, Austria; <sup>6</sup>Instituto OUF de Oncologia (I.C.O.), Lisbon, Portugal

Annals of Oncology 27 (Supplement 5): v28–v37, 2016  
doi:10.1093/annonc/mdw324



Ablazione intraduttale con radiofrequenza (RFA) ?

# BRACHITERAPIA



La **brachiterapia** (dal greco brachýs - corto), conosciuta anche come radioterapia interna o curieterapia, è una forma di radioterapia in cui una sorgente di radiazioni è collocata all'interno o vicino alla zona da trattare.

Per il Colangiocarcinoma

Sorgenti di Iridio-192 montate su un catetere vengono inserite all'interno del drenaggio biliare posizionato in precedenza.



PER GENTILE CONCESSIONE DI CRISTINA MOSCONI

*Acta Radiologica Oncology* 22 (1983) Fasc. 5

FROM THE DEPARTMENT OF RADIATION ONCOLOGY, MARYLAND INSTITUTE FOR EMERGENCY MEDICINE  
AND DEPARTMENT OF PATHOLOGY, UNIVERSITY OF MARYLAND HOSPITAL, BALTIMORE, MARYLAND 21201,  
USA.

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## CHOLANGIOCARCINOMA

A place for brachytherapy

T. PREMPREE, E. F. COX, W. SEWCHAND and C.-K. TANG

Radiol Med. 1994 Jul-Aug;88(1-2):79-85.

**[Percutaneous treatment of hilar cholangiocarcinoma completed by high-dose rate brachytherapy. Experience in the first 5 cases].**

[Article in Italian]

Righi D<sup>1</sup>, Maass J, Zanon E, Tettoni S, Orecchia R, Lazzari R, Ragona R, Gandini G.

After completing radiation therapy, control cholangiograms demonstrated in all cases improvement of neoplastic strictures. The first two patients we treated show no signs of tumor recurrence at 4 and 1 months, respectively, after endoscopic removal of the stents. The third patient is still bearing 2 Carey-Coons endoprotheses to be removed after 3 months. The last patient with supposedly partial success of brachytherapy, was treated with two Strecker nitinol stents.

**RIDUZIONE STENOSI**



Radiol Med. 2001 Jun;101(6):495-502.

**[Unresectable hilar cholangiocarcinoma: combined percutaneous and radiotherapeutic treatment].**

[Article in Italian]

Golfieri R<sup>1</sup>, Giampalma E, Muzzi C, Maffei M, Amore B, Grazia C, Frezza G, Galuppi A, Gavelli G.

**DISCUSSION AND CONCLUSIONS:**

Good results were observed in the patients that completed the protocol, mean survival was 7,5 months instead of 1,75 months as in patients that underwent only percutaneous drainage.

**AUMENTO DELLA SOPRAVVIVENZA MEDIA**

Multimodality

in vivo 20: 757-760 (2006)

Unresectable Hilar Cholangiocarcinoma:  
Approach with Percutaneous Treatment  
Associated with Radiotherapy

R. GOLFIERI<sup>1</sup>, E. GIAMPALMA<sup>1</sup>,  
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<sup>1</sup>Unità Operativa Radiologia Malpighi  
Azienda Ospedaliero-Universitaria Policlinico

in vivo 20: 757-760 (2006)

## Unresectable Hilar Cholangiocarcinoma: Multimodality Approach with Percutaneous Treatment Associated with ~~Radiotherapy and Chemotherapy~~

~~R. GOLFIERI<sup>1</sup>, E. GIAMPALMA<sup>1</sup>, M. RENZULLI<sup>1</sup>, A. GALUPPI<sup>2</sup>,  
L. VICENZI<sup>2</sup>, M.C. GALAVERNI<sup>1</sup> and A. CAPPELLI<sup>1</sup>~~

<sup>1</sup>Unità Operativa Radiologia Malpighi and <sup>2</sup>Unità Operativa Radioterapia,  
Azienda Ospedaliero-Universitaria Policlinico S. Orsola-Malpighi, 40138, Bologna, Italy

**IL TRATTAMENTO PERCUTANEO (brachiterapia; stent o protesi plastiche) ASSOCIATO A RADIOTERAPIA E CHEMIOTERAPIA È UNA VALIDA ALTERNATIVA ALLA CHIRURGIA PALLIATIVA**

ANTICANCER RESEARCH 33: 2747-2754 (2013)

## Unresectable Perihilar Cholangiocarcinoma: Multimodal Palliative Treatment

CRISTINA MOSCONI<sup>1</sup>, MATTEO RENZULLI<sup>1</sup>, EMANUELA GIAMPALMA<sup>1</sup>,  
ANDREA GALUPPI<sup>2</sup>, CATERINA BALACCHI<sup>1</sup>, GIOVANNI BRANDI<sup>3</sup>,  
GIORGIO ERCOLANI<sup>4</sup>, GIAMPAOLO BIANCHI<sup>5</sup> and RITA GOLFIERI<sup>1</sup>

<sup>1</sup>Radiology Unit, Department of Digestive Diseases and Internal Medicine,  
General Hospital Sant'Orsola Malpighi, University of Bologna, Bologna, Italy;  
<sup>2</sup>Radiation Therapy Unit, <sup>3</sup>Oncology Unit, <sup>4</sup>Liver and Multiorgan Transplant Unit and  
Department of Internal Medicine, Ageing, and Nephrology, University of Bologna, Bologna, Italy

ANTICANCER RESEARCH 33: 2747-2754 (2013)

## Unresectable Perihilar Cholangiocarcinoma: Multimodal Palliative Treatment

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<sup>2</sup>Radiation Therapy Unit, <sup>3</sup>Oncology Unit, <sup>4</sup>Liver and Multiorgan Transplant Unit and <sup>5</sup>Internal Medicine Unit,  
Department of Internal Medicine, Ageing, and Nephrology, University of Bologna, Bologna, Italy

**IL TRATTAMENTO PERCUTANEO (brachiterapia; stent)) ASSOCIATO A RADIOTERAPIA  
E CHEMIOTERAPIA RAPPRESENTA LO STATO DELL'ARTE DELLA TERAPIA PALLIATIVA**



**Linee guida**

**TUMORI DELLE VIE BILIARI**

| Grado di raccomandazione SIGN | Raccomandazione Clinica                                                                                                                                                                 | Forza della raccomandazione clinica |
|-------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|
| <b>D</b>                      | Approcci combinati di chemio-radioterapia o radioterapia esclusiva (SBRT) possono essere considerati in pazienti non resecabili                                                         | <b>Positiva debole (458)</b>        |
| <b>D</b>                      | Le tecniche ablative possono essere considerate per lesioni singole, di piccole dimensioni (<3cm), in pazienti non resecabili                                                           | <b>Positiva debole (460)</b>        |
| <b>D</b>                      | Nei pazienti con iCCA non resecabile TACE e TARE possono essere prese in considerazione come opzione terapeutica                                                                        | <b>Positiva debole (483)</b>        |
| <b>C</b>                      | La TACE non dovrebbe essere considerata nella gestione routinaria dei pazienti con iCCA non resecabile                                                                                  | <b>Negativa debole (465)</b>        |
| <b>D</b>                      | Nel pCCA non resecabile la RFA intraduttale può essere presa in considerazione come opzione terapeutica.                                                                                | <b>Positiva debole (487)</b>        |
| <b>B</b>                      | Nel pCCA non resecabile, la radioterapia ottenuta combinando ILBT e EBRT, seguita da posizionamento di stent metallico dovrebbe essere presa in considerazione come opzione terapeutica | <b>Positiva forte (492)</b>         |



# BRACHITERAPIA: LETTERATURA

491. Leung JT, Kuan R: Intraluminal brachytherapy in the treatment of bile duct carcinomas. *Australian Radiology*, 41: 151–54, 1997
- 492. Takamura A, Saito H, Kamada T et al.: Intraluminal low-dose-rate <sup>192</sup>Ir brachytherapy combined with external beam radiotherapy and biliary stenting for unresectable extrahepatic bile duct carcinoma. *Int J Radiat Oncol Biol Phys* 57:1357-1365, 2003
493. Ghafoori AP, Nelson JW, Willett CG et al.: Radiotherapy in the Treatment of Patients with Unresectable Extrahepatic CCA. *Int J Radiat Oncol Biol Phys* 81:654-659, 2010
494. Yoshioka Y, Ogawa K, Oikawa H et al.: Impact of intraluminal brachytherapy on survival outcome for radiation therapy for unresectable biliary tract cancer: a propensity-score matched-pair analysis. *Int J Radiat Oncol Biol Phys* 89:822-829, 2014
495. González D, Gouma DJ, Rauws EA et al.: Role of radiotherapy, in particular intraluminal brachytherapy, in the treatment of proximal bile duct carcinoma. *Ann Oncol* 10:215-220, 1999
496. Golfieri R, Giampalma E, Renzulli M et al.: Unresectable hilar CCA: multimodality approach with percutaneous treatment associated with radiotherapy and chemotherapy. *In Vivo* 20:757-760, 2006
497. Válek V, Kysela P, Kala Z et al.: Brachytherapy and percutaneous stenting in the treatment of CCA: a prospective randomised study. *Eur J Radiol* 62:175-179, 2007
498. Alden ME, Mohiuddin M.: The impact of radiation dose in combined external beam and intraluminal Ir-192 brachytherapy for bile duct cancer. *Int J Radiat Oncol Biol Phys* 1994;28:945-951.
499. Mosconi C, Renzulli M, Giampalma E et al.: Unresectable perihilar CCA: multimodal palliative treatment. *Anticancer Res* 33:2747-2753, 2013
500. Shinohara ET, Guo M, Mitra N et al.: Brachytherapy in the treatment of CCA. *Int J Radiat Oncol Biol Phys* 78:722-728, 2010

**CLINICAL INVESTIGATION**

**Bile Ducts**

**INTRALUMINAL LOW-DOSE-RATE  $^{192}\text{Ir}$  BRACHYTHERAPY COMBINED WITH EXTERNAL BEAM RADIOTHERAPY AND BILIARY STENTING FOR UNRESECTABLE EXTRAHEPATIC BILE DUCT CARCINOMA**

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KAZUHIDE HIRAMATSU, M.D.,\* SHUHEI TAKEUCHI, M.D.,\* MASAKAZU HASEGAWA, M.D.,\* AND  
NORIYUKI MIYAMOTO, M.D.\*

\*Department of Radiology, Asahikawa Kosei Hospital, Asahikawa, Hokkaido, †Research Center Hospital of Charged Particle Therapy, National Institute of Radiological Sciences, Chiba, Japan

**Purpose:** To evaluate the results of combined-modality therapy, including external beam radiotherapy, intraluminal  $^{192}\text{Ir}$ , and biliary stenting for extrahepatic bile duct carcinoma.

**Methods and Materials:** Between 1988 and 1998, 93 patients with unresectable extrahepatic bile duct carcinoma underwent definitive radiotherapy. The dose of external beam radiotherapy was 50 Gy in 25 fractions. Low-dose-rate  $^{192}\text{Ir}$  was delivered at a dose of 27–50 Gy (mean 39.2) at 0.5 cm from the source. An expandable metallic endoprosthesis was used to establish an internal bile passage.

**Results:** The median survival was 12 months, with a 1-, 3-, and 5-year actuarial survival rate of 50%, 10%, and 4%, respectively. Tumor length, hepatic invasion, and distant metastasis significantly affected survival. Ninety-six percent of patients could successfully remove external drainage catheters. The actuarial biliary patency rate for these patients at 1, 3, and 5 years was 52%, 29%, and 18%, respectively. Tumor length, tumor diameter and T stage were significantly associated with the patency rate. Mild-to-severe gastroduodenal complications were observed in 32 patients and were significantly associated with the active length of  $^{192}\text{Ir}$  and linear source activity. Eight patients had treatment-related biliary fistula.

**Conclusion:** Our combined-modality therapy provided reasonable local control and improved the quality of life of patients with extrahepatic bile duct carcinoma. Because none of the treatment characteristics had any impact on survival or biliary patency, lower dose levels and/or a localized target volume are recommended to minimize morbidity. © 2003 Elsevier Inc.

**RAGIONEVOLE CONTROLLO LOCALE DELLAMALATTIA ASSOCIATO AD UN MIGLIORAMENTO DELLA QUALITÀ DI VITA DEI PAZIENTE**



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500. Shinohara ET, Guo M, Mitra N et al.: Brachytherapy in the treatment of CCA. *Int J Radiat Oncol Biol Phys* 78:722-728, 2010

**LO SCHEMA TERAPEUTICO DI BRACHITERAPIA  
ASSOCIATA A  
STENT E RADIOTERAPIA ESTERNA  
AUMENTA LA SOPRAVVIVENZA**

**EJR**  
EUROPEAN JOURNAL OF RADIOLOGY

European Journal of Radiology 62 (2007) 175–179

[www.elsevier.com/locate/ejrad](http://www.elsevier.com/locate/ejrad)

**Brachytherapy and percutaneous stenting in the treatment  
of cholangiocarcinoma: A prospective randomised study**

**Vlastimil Válek<sup>a,\*</sup>, Petr Kysela<sup>b</sup>, Zdenek Kala<sup>b</sup>, Igor Kiss<sup>c</sup>, Jiří Tomášek<sup>c</sup>, Jiří Petera<sup>d</sup>**

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Received 26 January 2007; accepted 31 January 2007

*J Gastrointest Oncol* 2016;7(4):580-587

## Comparison of external beam radiation and brachytherapy to external beam radiation alone for unresectable extrahepatic cholangiocarcinoma

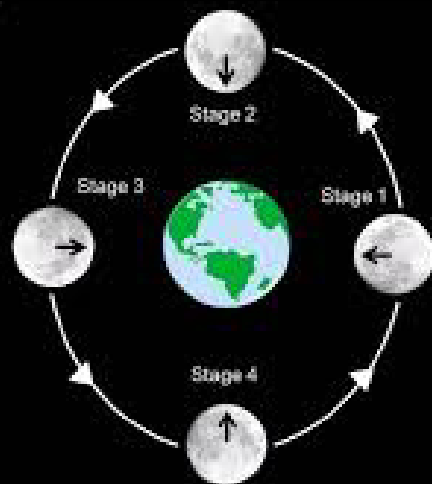
Dustin Boothe<sup>1</sup>, Zachary Hopkins<sup>2</sup>, Jonathan Frandsen<sup>1</sup>, Shane Lloyd<sup>1</sup>

**Results:** Of the 1,326 patients with unresectable EHC, 1,188 (92.9%) received EBRT only, while 91 (7.1%) received both EBRT and brachytherapy. Patients receiving combined modality radiation therapy were more likely to be treated prior to the year 2000. Median overall survival for patients receiving EBRT and EBRT plus brachytherapy was 9 and 11 months, respectively ( $P=0.04$ ). Cause specific survival was 12 months for those receiving EBRT only, and 15 months for those who received EBRT + brachytherapy ( $P=0.10$ ). Survival analysis performed on patients with locoregional disease only revealed a trend towards prolonged overall survival with those receiving EBRT + brachytherapy ( $P=0.08$ ). Multivariate analysis revealed grade and stage of disease were correlated with both overall survival and cause specific survival ( $P\leq 0.05$ ).

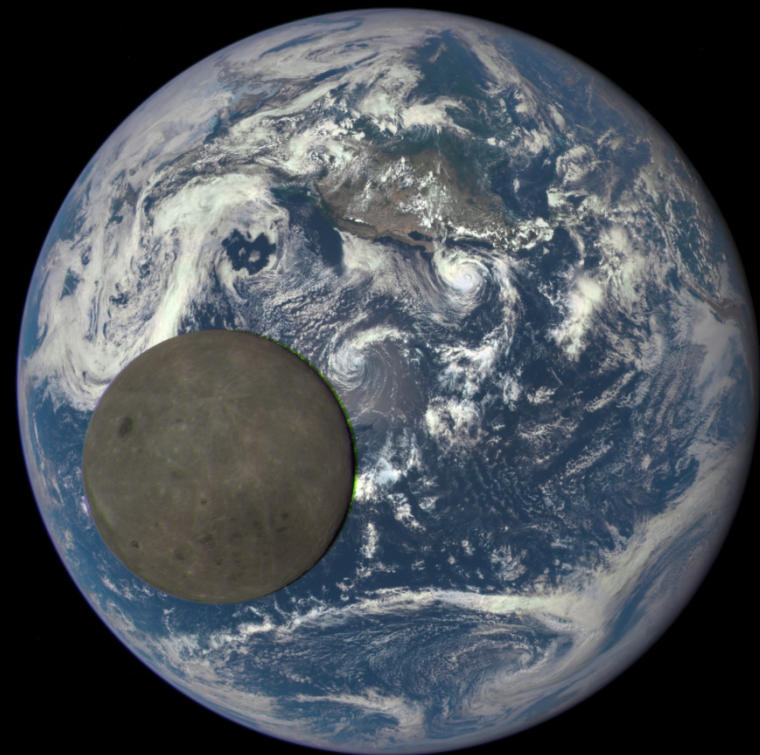
**Conclusions:** Among patients with unresectable EHC, the addition of brachytherapy to EBRT is associated with a prolonged median overall survival.

**DEI 1,326 PAZIENTI DEL REGISTRO SEER CON COLANGIOCARCINOMA NON RESECABILE SOLO 91(7,1%) HANNO FATTO RADIOTERAPIA E BRACHITERAPIA L'AGGIUNTA DELLA BRACHITERAPIA ALLA RADIOTERAPIA È ASSOCIATA AD UN INCREMENTO DELLE SOPRAVVIVENZA MEDIA**





The moon rotates one  
time for every revolution  
around the earth





**BACK**

# Clinical benefit of radiation therapy and metallic stenting for unresectable hilar cholangiocarcinoma

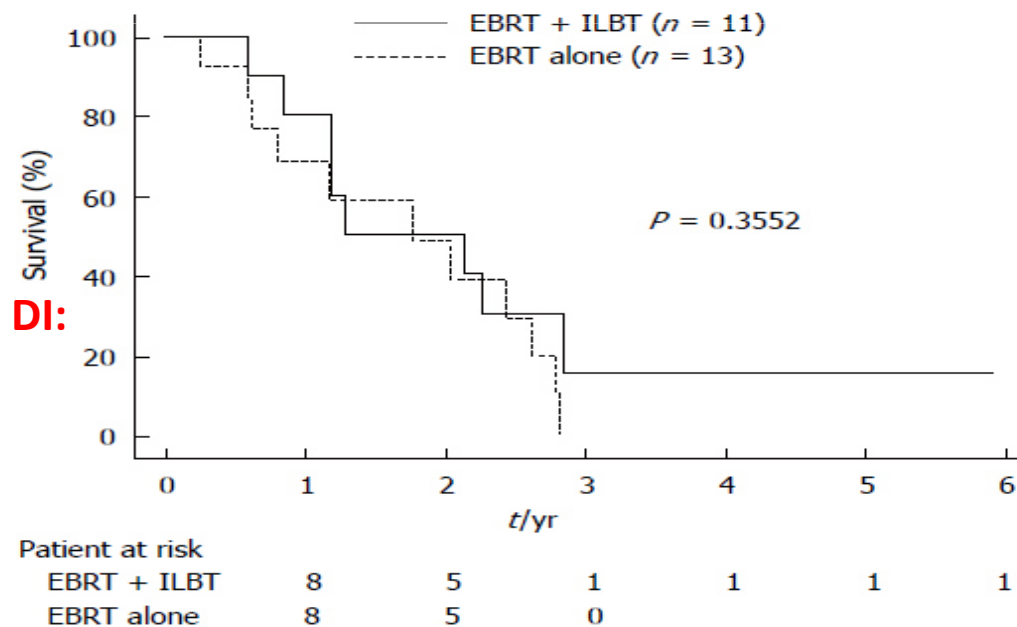
Isayama H *et al.*

May 21, 2012 | Volume 18 | Issue 19 |

To determine the efficacy of ILBT, we compared survival time and stent patency in the EBRT alone and EBRT plus ILBT groups. However, we found no significant difference in survival time between groups or for stent patencies.

**RADIOTERAPIA ESTERNA VS  
ESTERNA PIÙ INTERNA**

**NESSUNA DIFFERENZA IN TERMINI DI:  
SOPRAVVIVENZA MEDIA  
PERVIETÀ DEGLI STENT**

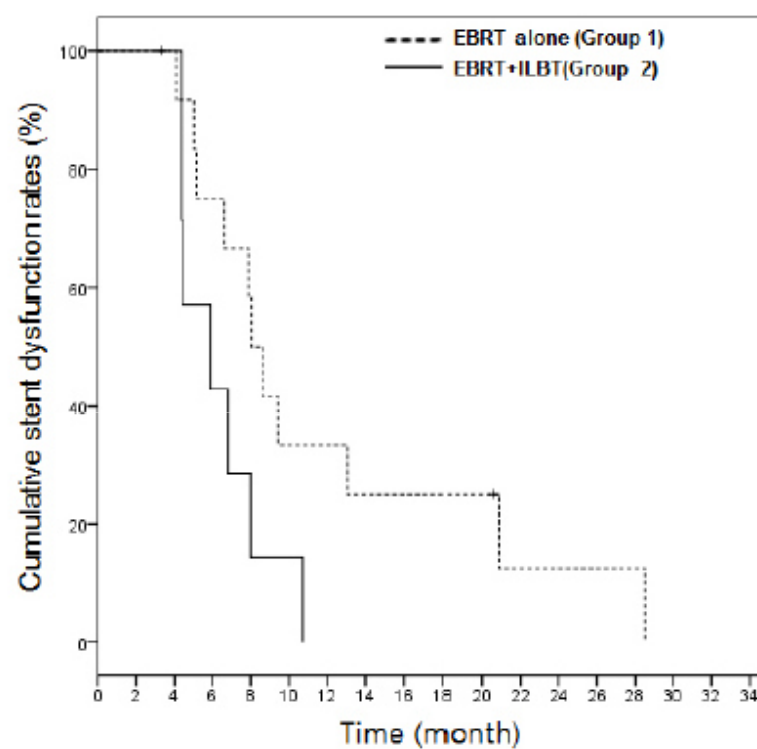
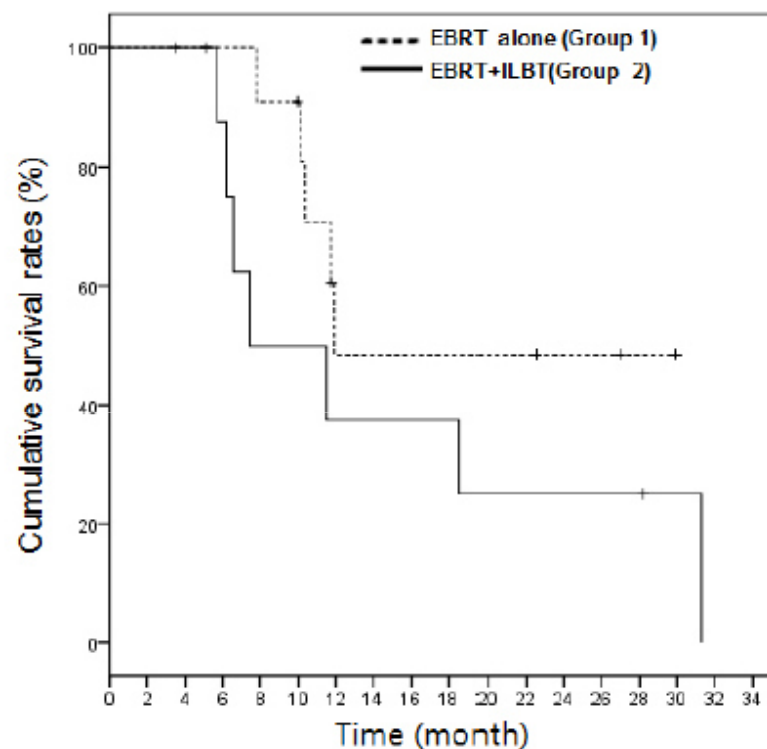


# The Efficacy of Intraluminal Brachytherapy as Palliative Therapy of Hilar Cholangiocarcinoma

Jin-Seok Park<sup>1</sup>, Seok Jeong<sup>1</sup>, Woo Chul Kim<sup>2</sup>, Don Haeng Lee<sup>1</sup>

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The dark side of the guidelines



## RADIOTERAPIA ESTERNA VS ESTERNA PIÙ INTERNA

Conclusions: E  
treatment effect

NESSUNA BENEFICIO:  
SOPRAVVIVENZA MEDIA  
PERVIETÀ DEGLI STENT

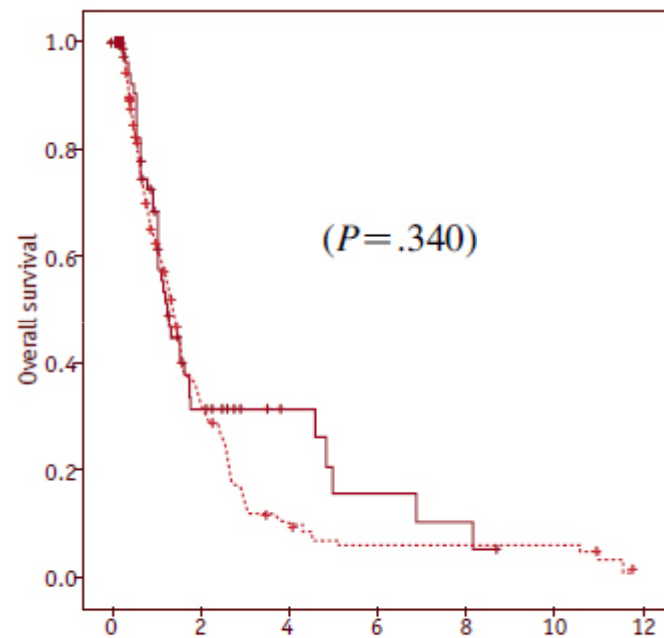
pared with the  
ocarcinoma.



Yoshioka et al. Volume 89 • Number 4 • 2014

International Journal of Radiation Oncology • Biology • Physics

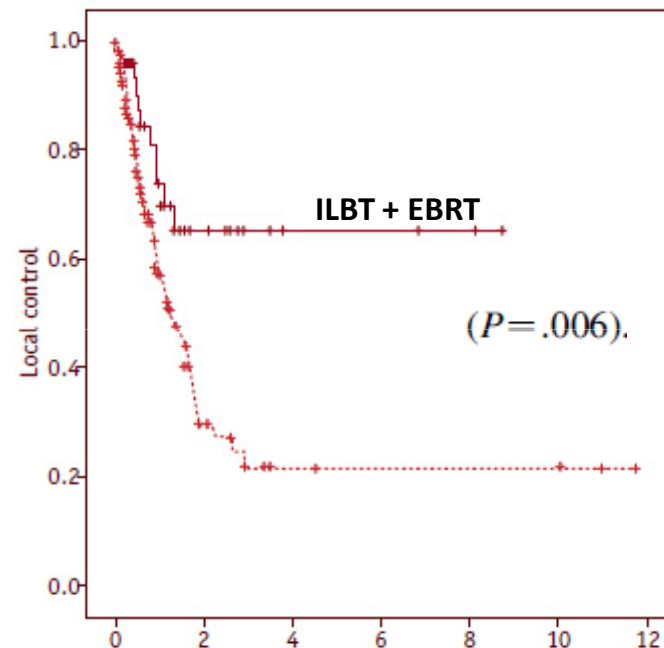
# Impact of Intraluminal Brachytherapy on Survival Outcome for Radiation Therapy for Unresectable Biliary Tract Cancer: A Propensity-Score Matched-Pair Analysis



Number at risk:

|       |     |    |
|-------|-----|----|
| ILBT+ | 56  | 14 |
| ILBT- | 153 | 35 |

**RADIOTERAPIA ESTERNA VS  
ESTERNA PIÙ INTERNA**



**NESSUN INCREMENTO NELLA SOPRAVVIVENZA  
MAGGIOR CONTROLLO LOCALE**

e addition of

# MODALITÀ DI TRATTAMENTO

|                | EBRT       |        |          | BT      |        |            | CT |
|----------------|------------|--------|----------|---------|--------|------------|----|
|                | SEDUTE     | DOSE   | QUANDO   | SEDUTE  | DOSE   | QUANDO     |    |
| Mosconi et al  | 25 /1.8 Gy | 46Gy   | DOPO BT  | 2/4-7Gy | 8-14Gy | PRIMA EBRT | SI |
| Takamura et al | 25/2 Gy    | 50Gy   | PRIMA BT |         | 39Gy   | DOPO EBRT  | NO |
| Isayama et al  | 30/1,8Gy   | 54Gy   | PRIMA BT | 4/6Gy   | 24Gy   | DOPO EBRT  | NO |
| Park et al     | 26/1,8Gy   | 47,4Gy | DOPO BT  | 3/6Gy   | 18Gy   | PRIMA EBRT | NO |
| Yoshioka et al | 25/2Gy     | 50Gy   |          | 3/6Gy   | 18Gy   |            | SI |

# Cholangiocarcinoma

Tushar Patel

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JANUARY 2006 VOL 3 NO 1

**NATURE CLINICAL PRACTICE**

GASTROENTEROLOGY & HEPATOLOGY

**DAT1 INSUFFICIENT  
CLINICAL TRIAL**

## **Radiation therapy**

Survival benefits from the use of conventional radiation therapy for residual or unresectable tumor have not been convincingly demonstrated. The use of external-beam radiation therapy or intraluminal brachytherapy has been described in several small series and might have a role in palliation. Currently, there are insufficient data to support the use of either approach as a routine therapy, but clinical trials to evaluate their role as part of multimodality regimens are warranted.<sup>12,65</sup>



Critical Reviews in Oncology/Hematology 90 (2014) 58–67

# Chemoradiation and brachytherapy in extrahepatic bile duct carcinoma

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**RUOLO INDEFINITO  
CLINICAL TRIAL**

CRITICAL REVIEWS IN

*Oncology  
Hematology*

Incorporating Geriatric Oncology

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## Chemoradiation and brachytherapy in extrahepatic bile duct carcinoma

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**INCORAGGIARE I PAZIENTI A PARTECIPARE A  
CLINICAL TRIAL**

## clinical practice guidelines

*Annals of Oncology* 27 (Supplement 5): v28–v37, 2016  
doi:10.1093/annonc/mdw324

### **Biliary cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up<sup>†</sup>**

J. W. Valle<sup>1</sup>, I. Borbath<sup>2</sup>, S. A. Khan<sup>3</sup>, F. Huguet<sup>4</sup>, T. Gruenberger<sup>5</sup> & D. Arnold<sup>6</sup> On behalf of the  
ESMO Guidelines Committee\*

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GUT 2012

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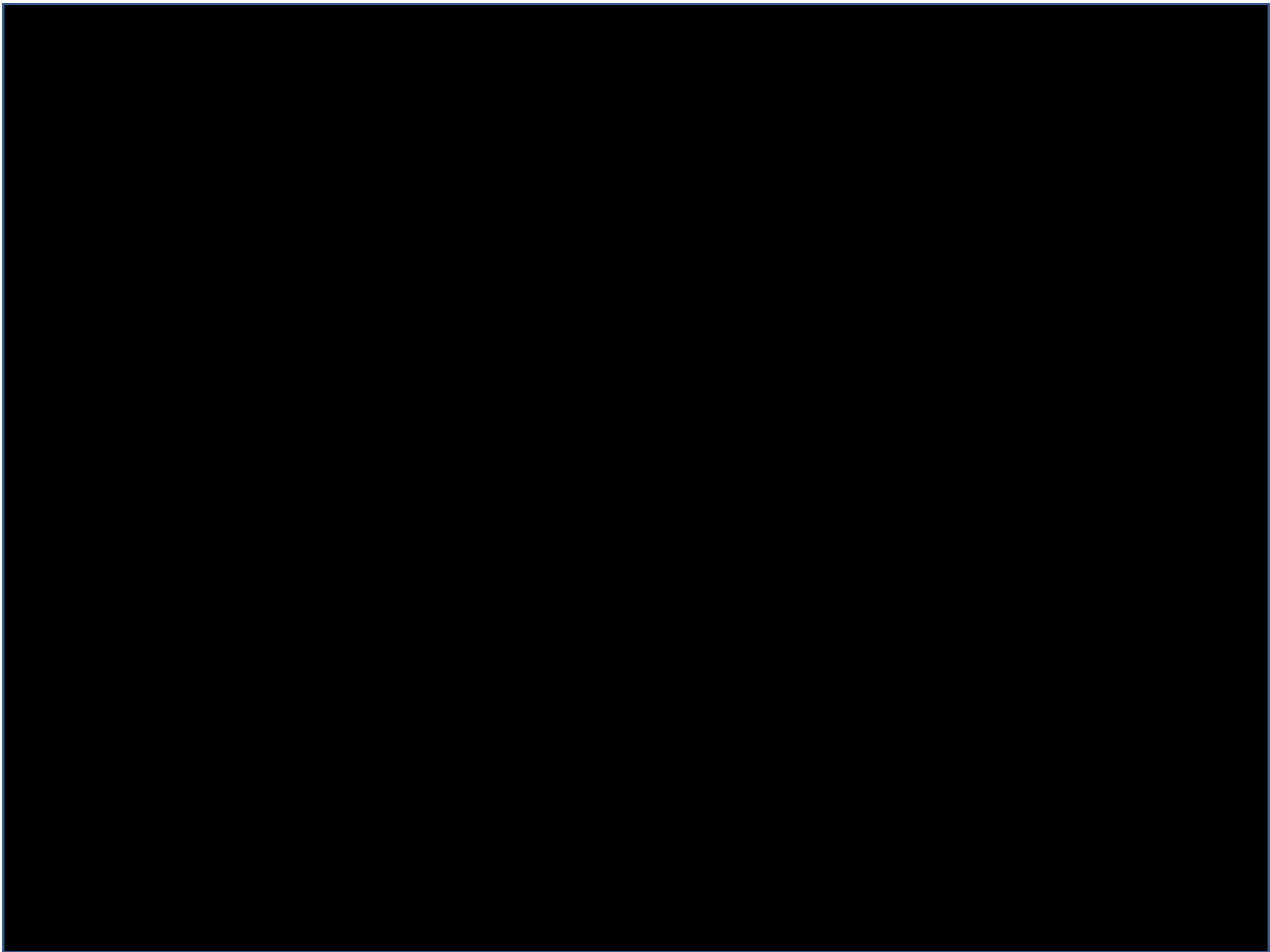
**INCORAGGIARE I PAZIENTI A  
PARTECIPARE A  
CLINICAL TRIAL**

Guidelines

## Guidelines for the diagnosis and treatment of cholangiocarcinoma: an update

~~Shahid A Khan,<sup>1</sup> Brian R Davidson,<sup>2</sup> Robert D Goldin,<sup>3</sup> Nigel Heaton,<sup>4</sup> John Karani,<sup>4</sup>  
Stephen P Pereira,<sup>5</sup> William M C Rosenberg,<sup>5</sup> Paul Tait,<sup>6</sup> Simon D Taylor-Robinson,<sup>1</sup>  
Andrew V Thillainayagam,<sup>1</sup> Howard C Thomas,<sup>1</sup> Harpreet Wasan<sup>7</sup>~~

# **RADIOFREQUENZA ENDODUTTALE**



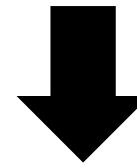


# ABLAZIONE INTRADUTTALE CON RADIOFREQUENZA: INDICAZIONI?

## CLINICAL TRIAL?

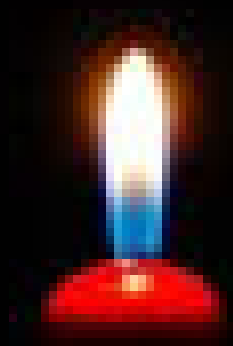
**NICE** National Institute for  
Health and Care Excellence September 2013

Endoscopic bipolar radiofrequency ablation for  
treating biliary obstruction caused by  
cholangiocarcinoma or pancreatic  
adenocarcinoma



Current evidence on the safety and efficacy of endoscopic bipolar  
radiofrequency ablation for treating biliary obstructions caused by  
cholangiocarcinoma or pancreatic adenocarcinoma is inadequate in quantity  
and quality.

**EVIDENZE INADEGUATE IN QUANTITÀ E QUALITÀ**



| Grado di raccomandazione SIGN | Raccomandazione Clinica                                                                                                                                                                | Forza della raccomandazione clinica |
|-------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|
| <b>D</b>                      | Approcci combinati di chemio-radioterapia o radioterapia esclusiva (SBRT) possono essere considerati in pazienti non resecabili                                                        | <b>Positiva debole (458)</b>        |
| <b>D</b>                      | Le tecniche ablative possono essere considerate per lesioni singole, di piccole dimensioni (<3cm), in pazienti non resecabili                                                          | <b>Positiva debole (460)</b>        |
| <b>D</b>                      | Nei pazienti con iCCA non resecabile TACE e TARE possono essere prese in considerazione come opzione terapeutica                                                                       | <b>Positiva debole (483)</b>        |
| <b>C</b>                      | La TACE non dovrebbe essere considerata nella gestione routinaria dei pazienti con iCCA non resecabile                                                                                 | <b>Negativa debole (465)</b>        |
| <b>D</b>                      | Nel pCCA non resecabile la RFA intraduttale può essere presa in considerazione come opzione terapeutica.                                                                               | <b>Positiva debole (487)</b>        |
| <b>B</b>                      | Nel pCCA non resecabile la radioterapia ottenuta combinando ILBT e EBRT, seguita da posizionamento di stent metallico dovrebbe essere presa in considerazione come opzione terapeutica | <b>Positiva forte (492)</b>         |

# COME FUNZIONA

## Catetere per radiofrequenza endobiliare tipo Habib™ EndoHPB

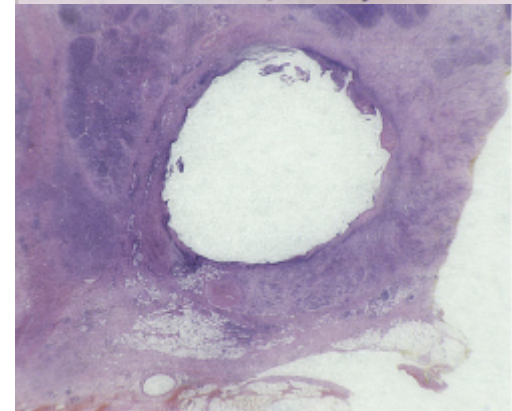
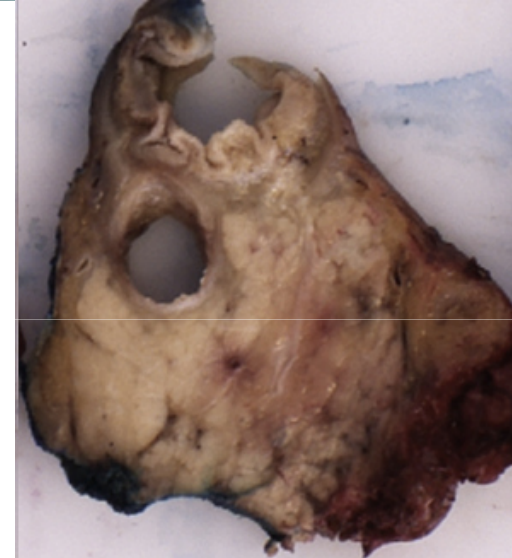
CATETERE BIPOLARE 8FR

INTRODUTTORE RACCOMANDATO 10Fr

Il catetere viene collegato ad un generatore di radiofrequenze  
Si posizionano gli elettrodi in sede di lesione e si procede alla  
radiofrequenza

Il generatore deve essere tarato per una potenza massima di  
10W (5-10W)

L'applicazione dura 90" se si vuole ripetere l'applicazione  
bisogna aspettare 60"





**Objective:** To demonstrate the safety of endobiliary bipolar radiofrequency ablation (RFA) in patients with malignant biliary obstruction and to report the 90-day biliary patency of this novel procedure.

**Design:** Open-label pilot study.

**Setting:** Single tertiary care unit.

**Patients:** A total of 22 patients with unresectable malignant bile duct obstruction.

**Interventions:** Bipolar RFA within the bile duct.

**Main Outcome Measurements:** Immediate and 30-day complications and 90-day stent patency.

**Results:** A total of 22 patients (16 pancreatic, 6 cholangiocarcinoma) were recruited between January 2009 and April 2010. Deployment of an RFA catheter was successful in 21 patients. SEMS placement was achieved in all cases of successful RFA catheter deployment. One patient failed to demonstrate successful biliary decompression after SEMS placement and died within 90 days. All other patients maintained stent patency at 30 days. One patient had asymptomatic biochemical pancreatitis, 2 patients required percutaneous gallbladder drainage, and 1 patient developed rigors. At 90-day follow-up, 1 additional patient had died with a patent stent, and 3 patients had occluded biliary stents.

**Limitations:** Cohort study.

**Conclusions:** Endobiliary RFA treatment appears to be safe. Randomized studies with prolonged follow-up are warranted.

**22 PAZIENTI SEMBRA ESSERE SICURO**

**Conclusion: Percutaneous intraductal RFA combined with metal stent placement is a technically safe and feasible therapeutic option for the palliative treatment of unresectable Bismuth types III and IV hilar cholangiocarcinoma. Its long-term efficacy and safety is promising, but needs further study via randomized and prospective trials that include a greater number of patients.**

**SEMBRA ESSERE SICURA E PROMETTENTE NELLE LESIONI TIPO BISMUTH III E IV**

SEMBRA ESSERE ASSOCIATA AD UN MIGLIORAMENTO DELLA SOPRAVVIVENZA

ORIGINAL ARTICLE

## Impact of Radiofrequency Ablation on Malignant Biliary Strictures: Results of a Collaborative Registry

Reem Z. Sharaiha · Amrita Sethi · Kristen R. Weaver · Tamas A. Gonda ·  
Raj J. Shah · Norio Fukami · Prashant Kedia · Nikhil A. Kumta ·  
Carlos M. Rondon Clavo · Michael D. Saunders · Jorge Cerecedo-Rodriguez ·  
Paola Figueroa Barojas · Jessica L. Widmer · Monica Gaidhane ·  
William R. Brugge · Michel Kahaleh

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analysis time

— SEER data — RFA

**Conclusion** Radiofrequency ablation is effective and safe in malignant biliary obstruction and seems to be associated with improved survival.

# CONCLUSIONI







IL PESO DELL'EVIDENZA  
CLINICAL TRIAL