admedico aps
Advanced Medico Equipment

admedico aps
Sanskevej 17
DK – 2960 Rungsted Kyst
Danmark
www.admedico.dk
Mail: mailto@admedico.dk
Tel: +45 4576 8620

Folketinget
Christiansborg
1240 København K
Att: Formand for Folketingets Sundhedsudvalg
Birthe Skaarup

Rungsted Kyst, den 19. februar 2007

Nye stråleterapi muligheder

Flere Europæiske lande har eller er i gang med at indføre InterOperativ RadioTherapy som en del af strålebehandlingsmulighederne.

InterOperativ RadioTherapy (IORT) er strålebehandling medens patienten er under operation. IORT er kendt, men har tidligere været begrænset af vanskelighederne i intern patienttransport, idet patienten i fuld bedøvelse skulle transporteres fra operationsstuens sterile miljø til strålerummet, som typisk ligger et godt stykke fra operationsstuen, og derefter tilbage for at færdiggøre operationen. Idag kan der fås udstyr der er godkendt til strålebehandling i operationsstuer uden særlige krav til afskærmning.

Vedlagt kopi af sammendrag over IOERT (IOERT er IORT med Electron Beam) behandlingsresultater contra resultater ved konventionel strålebehandling udarbejdet på basis af data fra ISIORT (International Society of InterOperative Radiation Therapy).

Resultaterne er ret tankevækkende. Danmark burde overveje IOERT også. Jeg kan notere, at Holland er ved at indføre IOERT som obligatorisk på en del af behandlingerne for rectalcancer.

Fordele ved IOERT:

- **Højere overlevelsesprocenter** – for nogle cancerbehandlinger markant
- **Færre patientskader** – mindre bestråling af rask væv
- **Reduktion / Eliminering af behandlinger i konventionel stråleterapi**

IOERT muliggør:

- **Strålebehandling i eksisterende operationsstuer – ingen særlig afskærmning**
- Kraftig Electron Beam der dækker de fleste IORT behandlinger
- Meget fin dosefordeling
- Mulighed for stort behandlingsareal Ø 3 – 10 cm
- **Økonomisk attraktiv behandlingsform**

Er der behov for yderligere information om IOERT så kan jeg kontaktes på telefon 4576 8620 eller mail hck@admedico.dk. Mere info kan også hentes på www.admedico.dk.

Med venlig hilsen

Hans Chr. Kjærgaard-Hansen

Vedlagt: ISIORT Pooled Analyse

SELECTED IOERT RESULTS

ISIORT POOLED ANALYSES

December 2006

Tumor Site	Patients	IOERT		Best Conventional	
		5-yr Local Control	5-yr Survival	5-yr Local Control	5-yr Survival
Locally advanced Rectal Cancer	**649**	**87%**	**60%**	< 50%	25%
Recurrent Rectal Cancer	**160**	**50%**	**37% 54% if R0 resection**	~ 30%	< 10%
Breast Boost [1]	**1097**	**99.6%**	**99.1% (DSS) 96.5% (OS) 93% (DFS)**	95.7%	90.1% (DFS)
Resectable Pancreatic Cancer	**185**	**73% w CRT**	**23%**	30-40%	10-15%
Soft Tissue Sarcomas	**255**	**78%**	**77%**	Comparable	Comparable
Retroperitoneal Sarcomas	**123**	**72% 100% if R0**	**58% 80% if R0**	~ 50%	~ 50%
Inoperable Pancreatic Cancer	**22 randomized, with and w/o sensitizer**	**NR**	**23% (3-year)**	NR	0% (3-year)
Single Dose Breast (APBI) [2]	**~1200**	**1 330 pts**	**0 330 pts**	1 341 pts	0 341 pts

(1) Bio-Boost compared to conventionally treated match pairs from U. of Salzburg
(2) Preliminary report on randomized results, made with only 22 months median follow-up.

Locally Advanced Rectal Cancer: Four participating institutions. Patients received preoperative chemoradiation therapy, followed by TME surgery + IOERT.

Recurrent Rectal Cancer: Data from single institution presented in March 2005 at the ISIORT Meeting. Pooled analysis data not yet analyzed, but will have over 300 patients. In The Netherlands, protocols are being written to require all recurrent rectal patients to receive IORT as part of their treatment.

Breast Boost: Six participating institutions. Patients received 10 Gy at the time of lumpectomy, followed by 5-6 weeks of EBRT 4 to 14 weeks after the surgery (25% of the patients had chemotherapy before EBRT radiation. 52% of patients had one or more adverse factors: young age, positive nodes, high tumor grade (G3), or large size (T3). Only four in-breast recurrences, none of them true recurrences. This is a disease specific survival of 99.1%. Median follow-up is 53 months. This boost, called the Bio-Boost, is now the standard of care at the U of Salzburg for all patients that are candidates for breast conserving therapy. Dr. Felix Sedlmayer estimates that if all eligible women in the U.S> received the bio-boost, more than 5000 mastectomies a year could be avoided.

Resectable Pancreatic Cancer: Pooled data form four institutions. Patients treated with three IOERT techniques: IOERT alone, IOERT plus post-operative EBRT with or without chemotherapy, and preoperative chemoradiation therapy followed by IOERT. Best results are preop CRT followed by IOERT. Local control in this disease generally means absence of pain for most of remainder of life.

Soft Tissue Extremity Sarcomas: Pooled data from three institutions. Surgery alone is not curative in this tumor and radiation doses in excess of 62 Gy must be given to control the tumor and preserve the limb. With IOERT, local control and survival and limb preservation equivalent or better than with other radiation boost techniques, such as brachytherapy boost (IOERT boost more uniform, easier to deliver) or EBRT boost (increases late toxicity). IOERT allows reduction of EBRT dose and that results in excellent limb function and reduced toxicity and reduced treatment time.

Retroperitoneal Sarcomas: Pooled data from three institutions. Two thirds of the patients had recurrent disease, and more than 50% of them had tumors larger than 10 cm. Despite these poor prognosticators, if the surgeon could achieve a complete macroscopic resection, local control and survival were excellent. Local failure in this tumor group is common. It is very hard to boost effectively with EBRT due to the location of the tumor site, and the large volume at risk. IOERT would appear to be the appropriate boost to combine with surgery and post-operative EBRT.

Inoperable Pancreatic Cancer: Randomized trial testing IORT +/- radiation sensitizer followed by post-operative EBRT. In inoperable pancreatic cancer, over 50% pf the patients die within 12 months, and there are virtually no three year survivors. Literature has only eight long-term survivors, all of whom received IOERT as part of their treatment. This is the first study to show benefit of radiation sensitizer. Sensitizers with IOERT could improve treatment results in other advanced disease.

Single Dose Breast IOERT (APBI): Randomized trial for women over 48years, small tumors (<2.5 cm), and node negative. The study is testing whether IOERT in this group of women of relatively low risk women can replace 5-7 weeks of post-operative radiotherapy. Study will be completed by end of 2006, and the results announced in 24 months when the data is mature. However, because many women have been treated with single dose off-protocol, it appears that the results of this APBI for wide excision surgery are equivalent to the results for standard BCT. Hospital is also starting a bio-boost trial with IOERT followed by hypofractionated EBRT, similar to the Phase II study currently being done at Mayo Clinic and the study that will be proposed by the ISIORT for the bio-boost. .Dr. Veronesi, internationally renowned breast surgeon, has stated that he believes that within a few years, IOERT will be the standard of care for breast cancer patients.