

Delbryst versus helbryst bestråling af tidlig brystkræft patienter i det randomiserede fase III DBCG PBI studie

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Baggrund, DBCG PBI trial

Risikoen for lokalt tilbagefald falder

Hovedparten af disse er lokaliseret i/tæt på det oprindelige tumorleje



Undersøge om man kan bestråle et mindre volumen i brystet uden at risikere flere bivirkninger eller flere tilbagefald



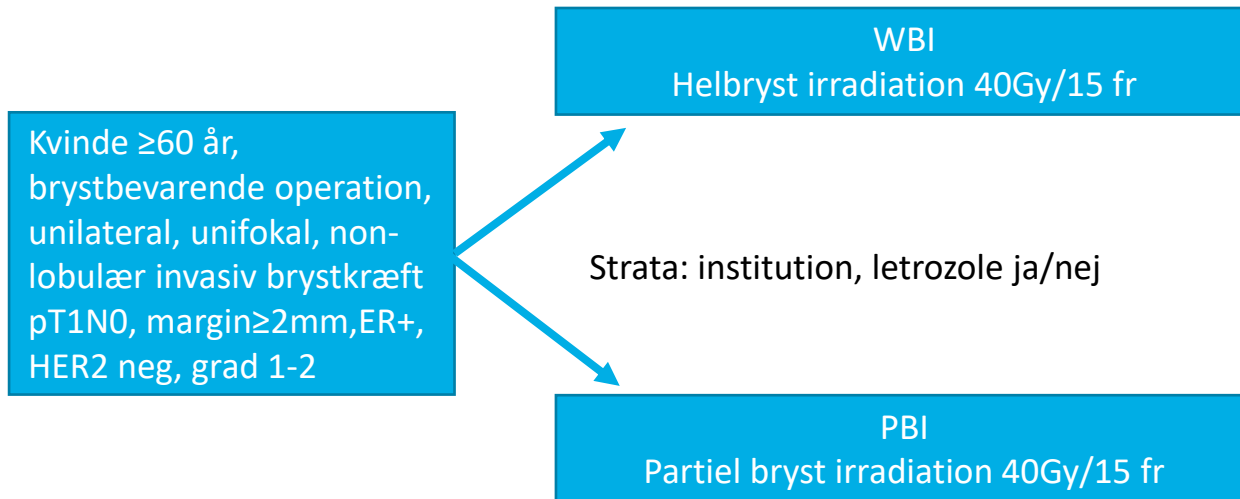
Adskillige PBI studier blev iværksat efter årtusindskiftet

Hypotese

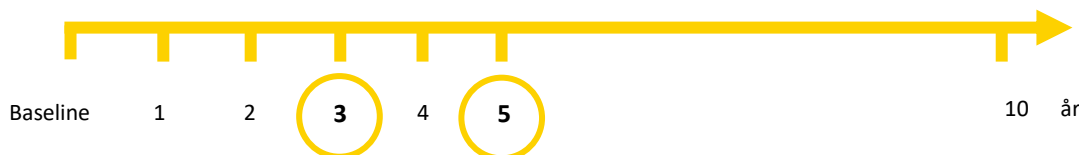
Delbryst bestråling leder ikke til mere fasthed i brystet efter 3 år i forhold til helbryst bestråling



Randomisering, DBCG PBI trial



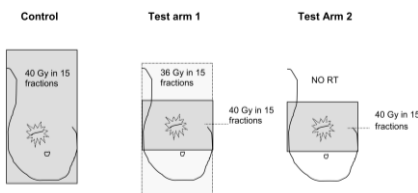
Primært endepunkt: bryst fasthed grad 2-3 ved 3 år efter stråler



Antagelser: 8% risiko for fasthed med WBI, mål at udelukke 10% øget med PBI
80% power, en-sidet test, significance niveau 5%, 7% drop-out

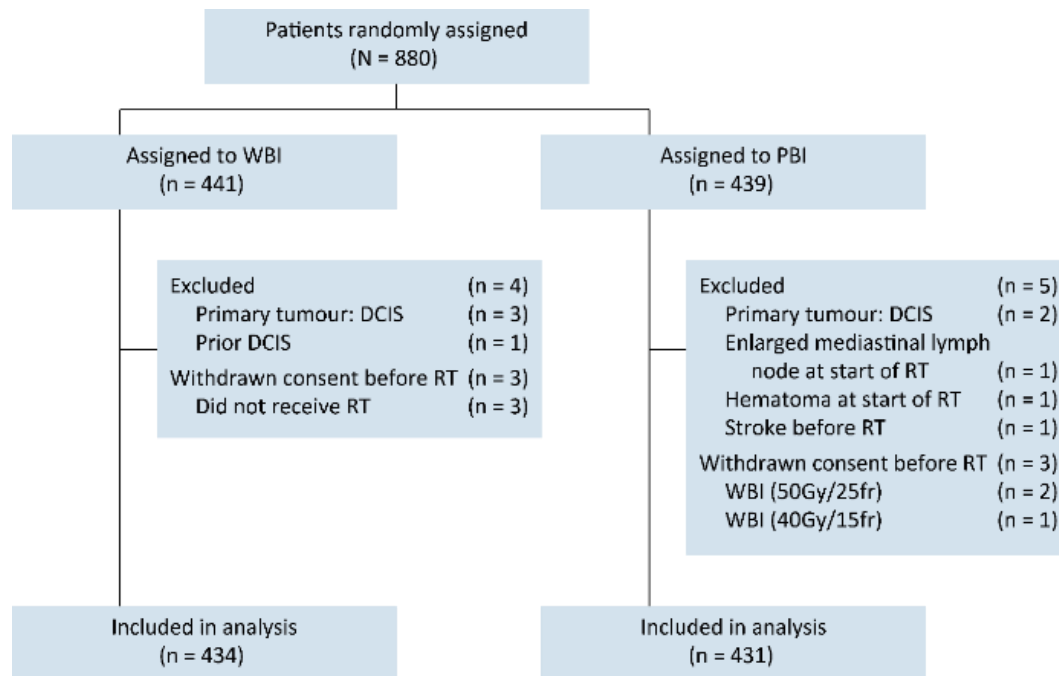
Nødvendigt antal patienter med 3 år data: 314 patienter OG inklusion fortsætter til de første data fra IMPORT LOW trial kendes (Marts 9, 2016)

The UK IMPORT LOW trial, ~2000 patienter



Coles C et al, Lancet 2017

CONSORT diagram



Afdeling	Antal patienter	
	WBI	PBI
Alle	441	439
Aarhus	219	214
Vejle	78	83
Odense	57	58
Aalborg	46	45
Rigshospitalet	41	39

Baseline karakteristik af patienterne

ESTRO 2021

	Whole Breast Irradiation (WBI) (n = 434)	Partial Breast Irradiation (PBI) (n = 431)
Age		
Median (range)	66 (60-86)	66 (60-83)
60-64	145 (33)	151 (35)
65-69	197 (45)	196 (45)
70-74	55 (13)	53 (12)
75-86	37 (9)	31 (7)
Laterality		
Right	224 (52)	201 (47)
Left	210 (48)	230 (53)
Breast size, ml (CTVp_breast)		
≤ 600	185 (43)	181 (42)
> 600	249 (57)	250 (58)
Target volume, ml (CTVp_whole-breast / CTVp_partial-breast)		
Median (IQR)	663 (443-994)	118 (81-173)
Tsize		
T1a	33 (8)	35 (8)
T1b	205 (47)	191 (44)
T1c	196 (45)	205 (48)
Histology		
Ductal	380 (88)	379 (88)
Lobular*	3 (1)	1 (0)
Other invasive	51 (12)	51 (12)
Grade		
Ductal, grade 1	223 (51)	225 (52)
Ductal, grade 2	154 (35)	151 (35)
Ductal, unknown	3 (1)	3 (1)
Not ductal	54 (12)	52 (12)

	Whole Breast Irradiation (WBI) (n = 434)	Partial Breast Irradiation (PBI) (n = 431)
Lymph nodes		
Negative	416 (96)	415 (96)
Isolated tumor cells	16 (4)	15 (3)
Micrometastasis ≤2mm*	2 (0)	1 (0)
ER		
1-9%	0 (0)	2 (0)
≥10%	434 (100)	429 (100)
HER2		
Negative	432 (100)	430 (99.8)
Positive*	1 (0)	0 (0.0)
Unknown*	1 (0)	1 (0)
Endocrine therapy		
No	198 (46)	196 (45)
Yes	236 (54)	235 (54)
Smoking		
Never/Prior	346 (80)	325 (75)
Current	88 (20)	106 (25)
BMI		
<18.5	10 (2)	3 (1)
18.5-24.9	182 (42)	195 (45)
25.0-29.9	151 (35)	132 (31)
≥30.0	91 (21)	100 (23)
Unknown	0 (0)	1 (0)

Data presented as no. (%) unless otherwise indicated.

Abbreviations: ER, estrogen receptor; HER2, human epidermal growth factor receptor 2; CTVp_breast, primary clinical target volume of the breast for WBI; CTVp_partial-breast, primary clinical target volume of the breast for PBI.

* Minor protocol violations.

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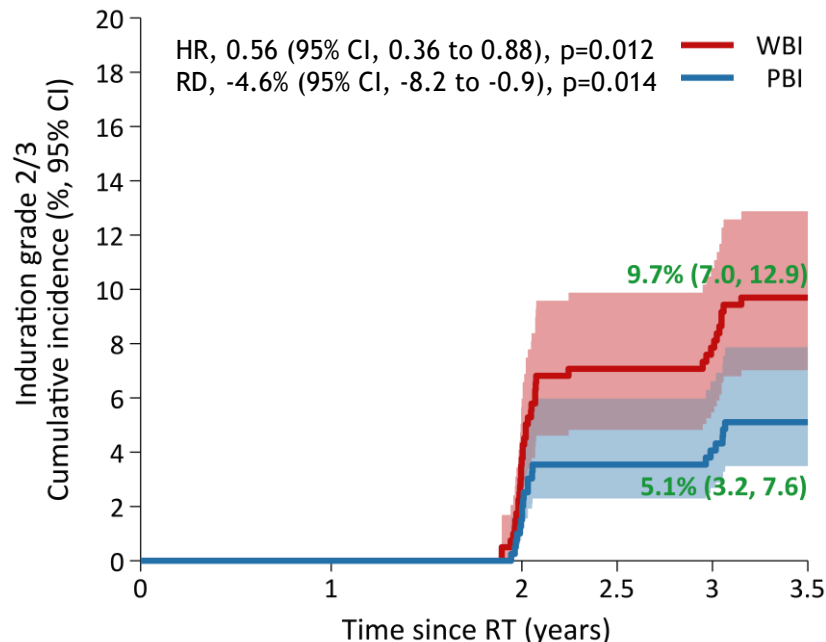
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* Minor protocol violations.

Det primære endepunkt: Kumulativ incidens af grad 2-3 fasthed

ESTRO 2021



Median follow-up for morbiditet
5.0 år (IQR 4.1-5.1)

No. at risk

WBI	401	401	381	356	346	330
PBI	399	399	384	364	357	338



Primære og sekundære endepunkter, bivirkninger

	År 3				År 5				Alle opfølgninger			
	Antal patienter med hændelse/Alle patienter (%)				Antal patienter med hændelse/Alle patienter (%)				Antal patienter med hændelse/Alle patienter (%)			
	WBI	PBI	OR (95% CI)	p	WBI	PBI	OR (95% CI)	p	WBI	PBI	OR (95% CI)	p
Induration	38/375 (10%)	19/368 (5%)	0.48 (0.27-0.85)	0.012	35/323 (11%)	19/312 (6%)	0.53 (0.30-0.95)	0.034	225/1866 (12%)	138/1840 (8%)	0.59 (0.43-0.82)	0.0018
Favourable overall cosmetic outcome	314/375 (84%)	326/368 (89%)	1.51 (0.99-2.30)	0.057	264/323 (82%)	280/312 (90%)	1.96 (1.23-3.10)	0.0044	1553/1866 (83%)	1635/1840 (89%)	1.58 (1.15-2.18)	0.0050
Telangiectasia	30/375 (8%)	19/368 (5%)	0.63 (0.35-1.13)	0.12	22/323 (7%)	21/312 (7%)	0.99 (0.53-1.83)	0.97	139/1866 (7%)	98/1840 (5%)	0.65 (0.43-0.98)	0.041
Dyspigmentation	33/375 (9%)	24/368 (7%)	0.72 (0.42-1.25)	0.24	13/323 (4%)	13/312 (4%)	1.04 (0.47-2.27)	0.93	246/1866 (13%)	132/1840 (7%)	0.46 (0.35-0.62)	<0.0001
Scar appearance	62/360 (17%)	53/356 (15%)	0.84 (0.56-1.25)	0.40	46/305 (15%)	38/300 (13%)	0.82 (0.51-1.30)	0.39	297/1798 (17%)	271/1786 (15%)	0.87 (0.64-1.17)	0.35
Oedema	7/375 (2%)	2/368 (1%)	NA	NA	5/323 (2%)	0/312 (0%)	NA	NA	34/1866 (2%)	10/1840 (1%)	0.30 (0.13-0.66)	0.0028
Pain	14/375 (4%)	14/368 (4%)	1.02 (0.48-2.17)	0.96	9/323 (3%)	11/312 (4%)	NA	NA	79/1866 (4%)	64/1840 (3%)	0.74 (0.44-1.23)	0.24
Use of analgesics	2/375 (1%)	5/368 (1%)	NA	NA	2/323 (1%)	2/312 (1%)	NA	NA	10/1866 (1%)	16/1840 (1%)	0.80 (0.20-3.20)	0.75
Sensibility change	7/375 (2%)	12/368 (3%)	NA	NA	9/323 (3%)	9/312 (3%)	NA	NA	57/1866 (3%)	50/1840 (3%)	0.72 (0.39-1.30)	0.27
Patient satisfaction, treated breast	340/369 (92%)	345/366 (94%)	1.40 (0.78-2.51)	0.26	300/321 (93%)	286/311 (92%)	0.80 (0.44-1.46)	0.47	1681/1810 (93%)	1684/1794 (94%)	1.30 (0.87-1.94)	0.20
Patient satisfaction, compared with contralateral breast	308/368 (84%)	321/363 (88%)	1.49 (0.97-2.28)	0.066	275/322 (85%)	276/311 (89%)	1.35 (0.84-2.15)	0.21	1537/1810 (85%)	1591/1790 (89%)	1.43 (1.05-1.95)	0.023

Events are defined as follows:

induration: palpable (grade 2) or clearly palpable; retraction of skin and fixation induration (grade 3); **favourable overall cosmetic outcome**: excellent (grade 0) or good (grade 1); **telangiectasia**: 1-4/cm² (grade 2) or >4/cm² (grade 3); **dyspigmentation**: both papilla and skin lighter or darker (grade 2) or dramatic difference in colour between sides either on the papilla and/or on skin (grade 3); **scar appearance**: visible and affects the cosmetic result to some degree (grade 2) or considerably (grade 3); **edema, breast**: symptomatic (grade 2) or secondary dysfunction (grade 3); **pain, breast**: often (grade 2) or always (grade 3); **use of analgesics**: often, mild (grade 2) or opioid needed (grade 3); **sensibility changes, breast**: moderate (grade 2) or severe (grade 3); and **patient satisfaction with treated breast only and compared with contralateral breast**: excellent (grade 0) or good (grade 1).

Abbreviations: NA, not analysed (<10 events in one or both treatment arms).

Median follow up for morbidity: 5.0 yr (IQR 4.1-5.1)

Primære og sekundære endepunkter, bivirkninger

	År 3				År 5				Alle opfølgninger			
	Antal patienter med hændelse/Alle patienter (%)				Antal patienter med hændelse/Alle patienter (%)				Antal patienter med hændelse/Alle patienter (%)			
	WBI	PBI	OR (95% CI)	p	WBI	PBI	OR (95% CI)	p	WBI	PBI	OR (95% CI)	p
Induration	38/375 (10%)	19/368 (5%)	0.48 (0.27-0.85)	0.012	35/323 (11%)	19/312 (6%)	0.53 (0.30-0.95)	0.034	225/1866 (12%)	138/1840 (8%)	0.59 (0.43-0.82)	0.0018
Favourable overall cosmetic outcome	314/375 (84%)	326/368 (89%)	1.51 (0.99-2.30)	0.057	264/323 (82%)	280/312 (90%)	1.96 (1.23-3.10)	0.0044	1553/1866 (83%)	1635/1840 (89%)	1.58 (1.15-2.18)	0.0050
Telangiectasia	30/375 (8%)	19/368 (5%)	0.63 (0.35-1.13)	0.12	22/323 (7%)	21/312 (7%)	0.99 (0.53-1.83)	0.97	139/1866 (7%)	98/1840 (5%)	0.65 (0.43-0.98)	0.041
Dyspigmentation	33/375 (9%)	24/368 (7%)	0.72 (0.42-1.25)	0.24	13/323 (4%)	13/312 (4%)	1.04 (0.47-2.27)	0.93	246/1866 (13%)	132/1840 (7%)	0.46 (0.35-0.62)	<0.0001
Scar appearance	62/360 (17%)	53/356 (15%)	0.84 (0.56-1.25)	0.40	46/305 (15%)	38/300 (13%)	0.82 (0.51-1.30)	0.39	297/1798 (17%)	271/1786 (15%)	0.87 (0.64-1.17)	0.35
Oedema	7/375 (2%)	2/368 (1%)	NA	NA	5/323 (2%)	0/312 (0%)	NA	NA	34/1866 (2%)	10/1840 (1%)	0.30 (0.13-0.66)	0.0028
Pain	14/375 (4%)	14/368 (4%)	1.02 (0.48-2.17)	0.96	9/323 (3%)	11/312 (4%)	NA	NA	79/1866 (4%)	64/1840 (3%)	0.74 (0.44-1.23)	0.24
Use of analgesic	2/375 (0%)	5/368 (1%)	NA	NA	2/323 (0%)	2/312 (0%)	NA	NA	12/1866 (0%)	16/1840 (0%)	0.22 (0.00-2.22)	0.75
Sensibility changes, breast												0.27
Patient satisfaction, treated breast												0.20
Patient satisfaction, compared with contralateral breast												0.023

Konklusion: PBI giver mindre fasthed i brystet, telangiectasier, dyspigmentering, ødem og bedre patienttilfredshed og globalt kosmetisk resultat indenfor de første 5 år

Events are defined as follows:

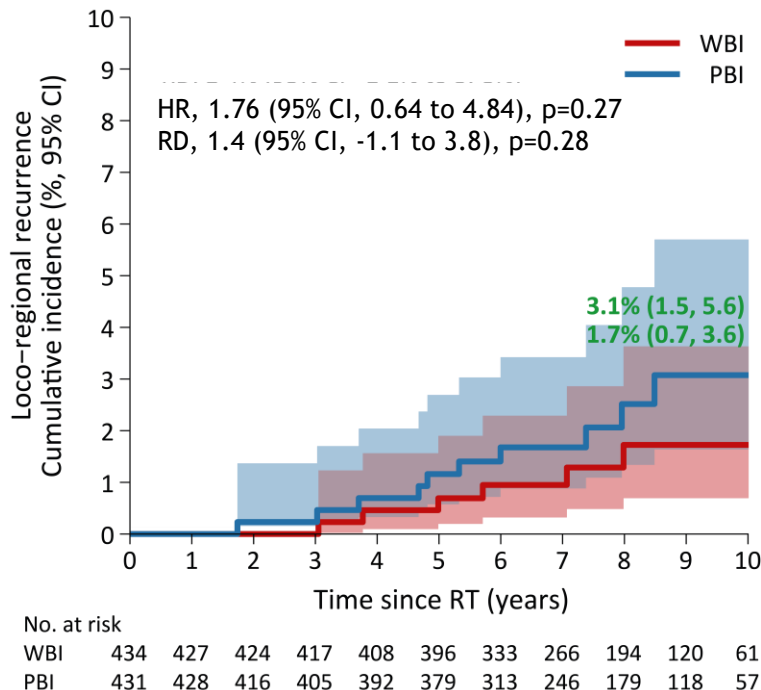
induration: palpable (grade 2) or clearly palpable; retraction of skin and fixation induration (grade 3); **favourable overall cosmetic outcome:** excellent (grade 0) or good (grade 1); **telangiectasia:** 1-4/cm² (grade 2) or >4/cm² (grade 3); **dyspigmentation:** both papilla and skin lighter or darker (grade 2) or dramatic difference in colour between sides either on the papilla and/or on skin (grade 3); **scar appearance:** visible and affects the cosmetic result to some degree (grade 2) or considerably (grade 3); **edema, breast:** symptomatic (grade 2) or secondary dysfunction (grade 3); **pain, breast:** often (grade 2) or always (grade 3); **use of analgesics:** often, mild (grade 2) or opioid needed (grade 3); **sensibility changes, breast:** moderate (grade 2) or severe (grade 3); and **patient satisfaction with treated breast only and compared with contralateral breast:** excellent (grade 0) or good (grade 1).

Abbreviations: NA, not analysed (<10 events in one or both treatment arms).

Median follow up for morbidity: 5.0 yr (IQR 4.1-5.1)

Kumulativ incidens af loco-regional tilbagefald

ESTRO 2021



Total 16 loco-reg tilbagefald (6 WBI, 10 PBI)

13 af de 16 var lokale, og 3 af dem vurderet nye primære (1 WBI, 2 PBI) → 10 "sande" lokale tilbagefald (4 WBI, 6 PBI)

Modsidig brystcancer: 20 patienter (19 invasiv, 1 DCIS; 7 WBI, 13 PBI)

Median follow up for cancer hændelser 7.6 yr (IQR 6.1-9.2)

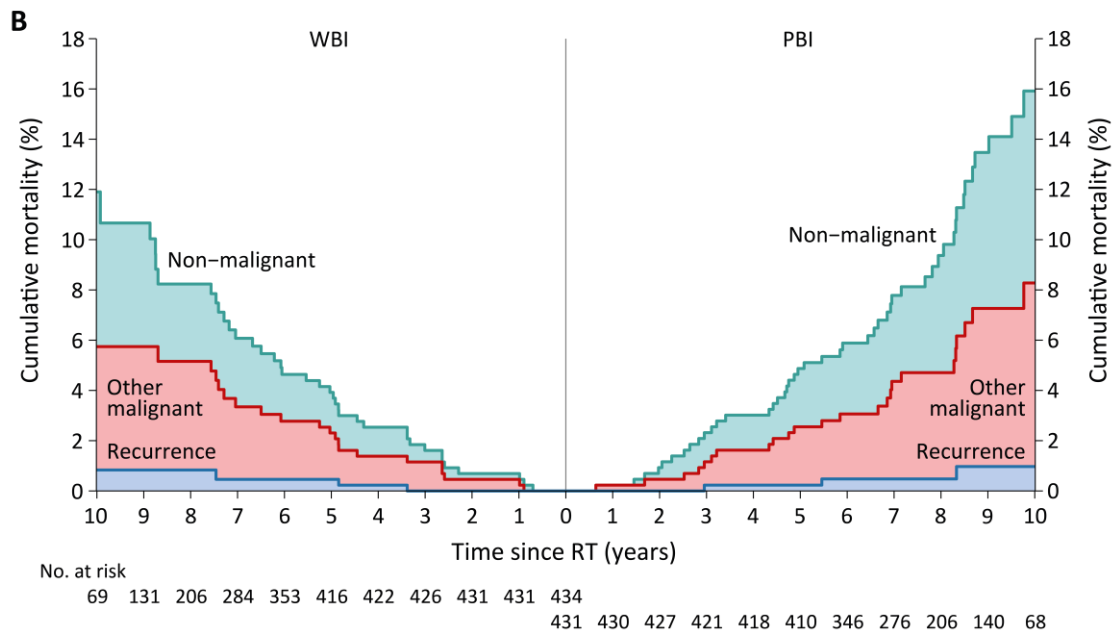
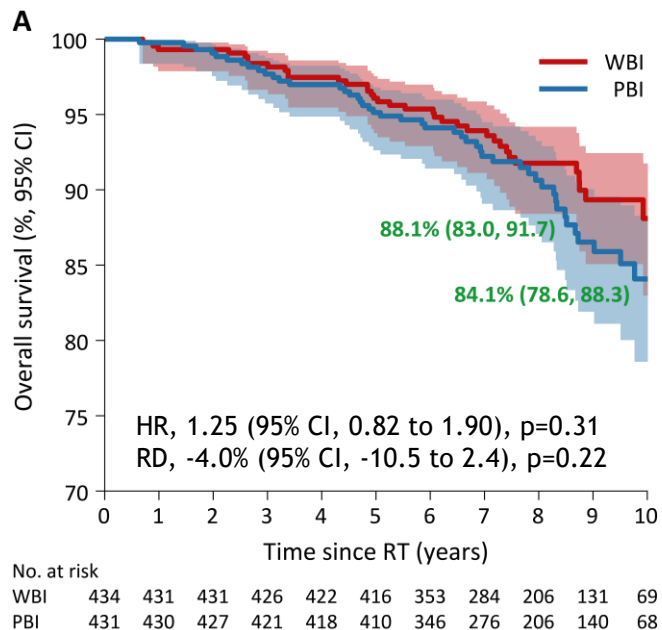
HR, hazard ratio; RD, risk difference at 10 years calculated as incidence with PBI minus incidence with WBI



DBCG

Danish Breast Cancer Cooperative Group

Overlevelse & Kumulativ dødelighed fordelt på årsag



Konklusion, DBCG PBI trial



Moderat hypofraktioneret PBI 40Gy/15fr til tidlig brystkræft øger ikke risikoen for fasthed i brystet

Såvel mht bivirkninger som mht tilbagefald kunne man ikke finde en undergruppe, hvor PBI ledte til øget risiko sammenlignet med WBI

PBI har været DBCG standard til udvalgte kvinder siden April 2016

Undladelse af PBI testes nu i det randomiserede DBCG RT Natural trial, hvor der er samme inklusions-krav, og så trækkes lod mellem PBI versus ingen PBI



DBC

CG Danish Breast Cancer Cooperative Group