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Original Article

Economic evaluation and budget-impact of accelerated partial breast irradiation (APBI) versus standard or hypofractionated whole breast irradiation (WBI) in postmenopausal women with early-stage breast cancer. Results from the French SHARE randomized trial

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ABSTRACT

Purpose: This economic evaluation reports the incremental cost-utility ratio and national budget impact in France of accelerated partial breast irradiation (APBI) vs standard or hypofractionated whole breast irradiation (WBI) in breast cancer patients at low risk of local recurrence.
Materials and methods: We compared 490 women randomized to the APBI (ten fractions delivered twice daily over one week) with 488 women in the WBI arm (one fraction per day delivered five days per week over three or six weeks). We took the perspective of the French national health insurance with a three-year time horizon. The outcome was quality-adjusted life years (QALYs). The incremental cost-effectiveness ratio was estimated and uncertainty was explored by probabilistic bootstrapping. Transportation and sick leave costs were added in a sensitivity analysis and a national budget impact analysis based on the incidence of breast cancer estimates in France performed.
Results: At three years, the average cost per patient was €2,549 (±1,954) in the APBI arm and €4,468 (±1,586) in the WBI arm (p-value < 0.001), radiotherapy was the main driver of the difference between the two arms. No significant difference was found in QALYs. For an average of 60,000 new cases of breast cancer diagnosed annually in France, 28,000 would be eligible for treatment with APBI. A 100% uptake of APBI would result in a yearly30 million€ cost saving.
Conclusion: APBI for the treatment of postmenopausal women with early-stage breast cancer is cost saving, with no difference in outcome measured by QALYs.
 Radiotherapy and Oncology 187 (2023) 109818

Breast cancer is the most common and deadliest cancer in women in the world (26% of all incident female cancers). In 2020, the annual number of new cases was estimated at 58,083 in France and the number of deaths at 14,183[1]. According to French data for the period 2009–2015, the number of breast cancers cancers limited to the breast, breast and nodes, or with distant metastases were 59 %, 29 % and 13 % respectively [2].

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Breast-conserving therapy consists of surgical excise of the whole tumor while preserving the breast. This treatment depends mainly on the size of the cancer in relation to the size of the breast. For a long time, post-operative external beam whole breast irradiation (WBI) was considered as the standard of care to reduce the risk of recurrence. This irradiation is not always easy to perform because of the age of the patients, their continued professional activity, or their distance from the treatment centers. Based on this observation, hypofractionated therapies have been developed to reduce the duration of treatment. Murray et al.[3] studied the Fast-Forward, five-fraction schedule of adjuvant therapy delivered in one week (one fraction per day. Fast-Forward was non-inferior to the standard of care of 40 Gy in 15 fractions over three weeks, this schedule was implemented in all French radiotherapy centers. In terms of radiation volume, Fast-Forward treats the whole breast, unlike APBI which treats only the tumor bed. In radiotherapy, it is recognized that high doses in fractions on large volumes can be deleterious on the late toxicity of healthy tissues. APBI is therefore still relevant for women with a large breast size. Over the past decade, studies have been conducted to determine whether limiting radiation therapy to the tumor bed is as safe as whole breast radiation therapy.

APBI trials are characterized by heterogeneity of inclusion criteria and stratification factors [4] and only a limited number of these trials have planned cost and cost-effectiveness analyses.

In 2020, the treatment of breast cancer cost 3.6. billion euros in France, with significant annual growth in spending [5]. As such, new strategies in breast cancer treatment must focus on outcomes and costs. ABPI is therefore an option for selected women whose profile has been defined in the ASTRO-RTOG and ESTRO consensus [6,7].

The French SHARE study is one of the first non-inferiority trials designed to compare APBI to WBI [4]. Briefly, SHARE was a prospective, randomised, controlled open-label trial conducted in 34 centres in France. From December 2010 to July 2015, it included 1,006 postmenopausal women older than 50 years and treated conservatively for breast cancer at low risk of local recurrence. Women were randomised to receive either APBI or Standard external WBI. APBI was performed in 10 fractions (34 to 40 Gy) delivered twice per day over one week. Standard external WBI included standard fractionation in 25 fractions (50 Gy) followed by a tumor bed boost in 8 fractions (16 Gy), one fraction per day delivered five days per week, or hypofractionated radiotherapy in 15 fractions (40 Gy) or 16 fractions (42.5 Gy), one fraction per day delivered five days per week. We present the results of the trial-based cost-effectiveness analysis comparing the cost and utility of the two arms with a time horizon of three years.

Materials and methods

Trial design and patients

We performed a single-trial based economic evaluation. The methods set for the SHARE trial have been previously described [4]. The trial included menopaused women aged > 50 years, with unifocal invasive carcinoma < 2 cm, all histopathologic grades, clear lateral margins > 2 mm, pN0 and pN(i +);surgical clips in the tumor bed placed during surgery (4 to 5 clips) 11; no prior breast or mediastinal radiotherapy. Patients with T2 and T3 were excluded.

The primary endpoint of the SHARE trial was the rate of local recurrence at five years. Data for the economic analysis at three years were prospectively collected during the trial in specific report forms, and are reported in accordance with the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement [8].

Registration and ethics

The study protocol was registered in the ClinicalTrials.gov registry (NCT01247233). This study was approved by ethics committee Hôpital de BICÊTRE, 78, rue du Général LECLERC. Sponsor's reference: RTS 02/0110-ID-RCB: 2010-A00243-36. All participants signed a written informed consent to participate in the study.

Costs

Only direct costs were estimated in the main analysis from the French national health insurance perspective using published official French tariffs in 2021 [9]. We assumed that all women were treated in public radiotherapy centers and they had no out of pocket costs. Transportation costs and daily compensation for sick leave paid by the health insurance were added in a sensitivity analysis [10].

Costs were calculated based upon the number of radiation fractions, rehospitalizations transport to the radiotherapy department, and sick leave [11]. Unit costs are shown in Table 1.

Effectiveness

The effectiveness was expressed as the difference in QALYs between the two arms during the three-year follow-up period. QALYs are calculated by weighting the years of life for a patient with their quality-of-life (QoL) score or utility. These QoL utility values were collected at baseline, three and six months, then at one, two and three years using the EQ-5D-5L health-related quality of life questionnaire [12]. The EQ-5D-5L comprises a descriptive system which is composed of five health dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) with five levels of health state (no problems to extreme problems). The participant's answers were combined to produce a utility value from the country specific value set. The French EQ-5D-5L value set was used in this economic study and has utility between − 0.525 (worst possible health) and 1 (best possible health) [13].

Economic evaluation

Costs and QALYs were assessed in both arms at three years and a discount rate of 2.5% was applied for results beyond the first year [14]. A discount rate is used as a 'time weighting' to devalue the future: the stronger the preference for the present, the higher the time weighting. An incremental cost-effectiveness ratio (ICER), or cost per QALY gained was calculated. Total costs for each arm were calculated by summing each individual patient cost. Incremental

Table 1
Unit costs used for economic evaluation.

Item	Value (€)	Source
Radiotherapy treatment		
• Irradiation preparation package	973	National tariffs
• Daily fee for radiotherapy treatment sessions	132	National tariffs
Transportation		
Public transport	2	National tariffs
Ambulance	90	Health Insurance data
Ambulance / taxi	33	Health Insurance data
Taxi	56	Health Insurance data
Personal vehicles	18	Health Insurance data
Rehospitalizations at 3 years	490−29,071	National tariffs
Daily compensation for sick leave	46	National tariffs

costs were reported as the difference in per-patient costs between arms. Incremental effects were defined as the difference in average QALYs between arms.

A budget-impact analysis of implementing of the APBI strategy in all French radiotherapy departments over a three-year horizon (2023 to 2025) was performed. The annual target population was all postmenopausal women older than 50 years recently diagnosed with breast cancer. In 2020, the number of new cases of breast cancer was estimated at 58,083 in France, including 80% amongst those aged 50 and over [1]. The number of breast cancers limited to the breast was 59% [2]. We assumed: (i) all women older than 50 years are menopausal, (ii) the variation in the incidence rate is 0.6% per year [15], (iii) 70% of women with a breast cancer limited to the breast are treated with breast conserving therapy [16].

Statistical analysis

The statistical analyses were performed on the intention-to-treat (ITT) population and on the population as treated for efficacy. Multivariate imputation by chained equations (MICE) was used to process missing data [17,18]. Imputed datasets were generated using predictive mean matching from a set of imputation models.

Cost and QALY data were expressed as mean ± standard deviation. Between arms, the difference in rehospitalizations was compared with a Poisson model or by negative binomial regression depending on the variance and the mean. Costs were compared with a permutation test. Other quantitative data were compared using Student's t-test. Where the assumption of equal variances was not met, a Welch correction was applied. The non-parametric Mann-Whitney test was carried out in the case of non-normal distribution.

The uncertainty of the results was analyzed using a nonparametric bootstrap which provided multiple estimates of the ICER by randomly resampling the patient population 1,000 times. Results were presented as a scatter plot of 1,000 ICERs on the cost-effectiveness plane. The 95% confidence intervals (95% CI) were estimated with this bootstrap technique. A p-value less than 0.05 was considered significant. All health economic analyses were done with R version 4.0.1 (The R Foundation) [19].

Results

Out of 1,006 patients with early-stage breast cancer enrolled in the SHARE trial, 28 were excluded from the economic study due to withdrawal of consent. The median follow-up period was 2.87 years (91% of patients had a three-year follow-up).

Of the 978 patients included in the ITT analysis, 490 were randomly assigned to receive APBI and 488 to receive WBI (213 or 44% with Standard radiotherapy and 275 of 56% with Hypofractionated radiotherapy). On the population as-treated for efficacy, the number of patients was 396 and 579 (304 with Standard radiotherapy and 275 with Hypofractionated radiotherapy), respectively.

Results are presented in Table 2 for the ITT analysis and in Supplementary table 1 for the as-treated for efficacy analysis.

In the ITT population, the average number of radiotherapy fractions was 13.3 (±7.4) in the APBI arm and 22.8 (±8.6) in the WBI arm (p-value < 0.001). Among the 490 patients in the APBI arm, 97 (20%), treated outside the protocol, received more than ten radiotherapy fractions, including 49 who received 33 radiotherapy fractions.

Costs

In the ITT population, the average 3-year cost per patient was €2,549 (±1,954) in the APBI arm and €4,468 (±1,586) in the WBI arm, i.e., a mean difference of €-1,919€ (95% CI: −2,148; −1,704; p-value < 0.001).

Including transportation costs and daily compensation for sick leave increased the 3-year cost to €3,319 (±2,655) for the APBI arm and €6,325 (±2,562) for the WBI arm, i.e., a mean difference of €-3,006 (95% CI: −3,339; −2,664; p-value < 0.01). Regarding transport to the radiotherapy department, 40% of patients travelled by personal vehicle, 33% by taxi, 11% o by public transport, 10% by ambulance, 4% by ambulance taxi, and 2% by foot.

Effectiveness

In the ITT population, the average QALY at three years was 2.38 (±0.63) in the APBI arm versus 2.38 (±0.64) in the WBI arm. Utility scores obtained during follow up are described in the supplementary material Table 2.

ICER

The three-year ICER was €319,833/ QALY. The set of ICERs estimated by non-parametric bootstrap are presented by the scatterplot on the cost-effectiveness plane in Figure 1 for ITT; 56% of these ICERs were located in the bottom right-hand quadrant. The

Table 2
Per-patient cost (discounted) in € and effectiveness result by randomization arm over a 3-year period (intention-to-treat analysis).

	APBI arm (N = 490)	WBI arm (N = 488)	P-value
QALYs	2.383 (±0.633)	2.377 (±0.639)	0.964
Number of radiotherapy fractions	13.3 (±7.4)	22.8 (±8.6)	**< 0.001**
Number of rehospitalizations λ	0.06 (±0.55)	0.03 (±0.17)	0.277
Costs (€)			
Main analysis			
Radiotherapy	2,369 (±1,300)	4,323 (±1,228)	**< 0.001**
Rehospitalisations λ	180 (±1,494)	145 (±1,137)	0.678
• Day hospitalizations	*28 (±276)*	*29 (±298)*	*0.969*
• Overnight hospitalizations	*152 (±1,470)*	*116 (±1,099)*	*0.665*
Total 3-year costs	2,549 (±1,954)	4,468 (±1,586)	**< 0.001**
Sensitivity analysis			
Transportation	657 (±854)	1,663 (±1,312)	**< 0.001**
Sick leave	113 (±759)	194 (±1,104)	0.181
Total 3-year costs†	3,319 (±2,655)	6,325 (±2,562)	**< 0.001**

† Including radiotherapy, rehospitalizations, transportation and sick leave costs.
λ: including breast surgery or pain management.

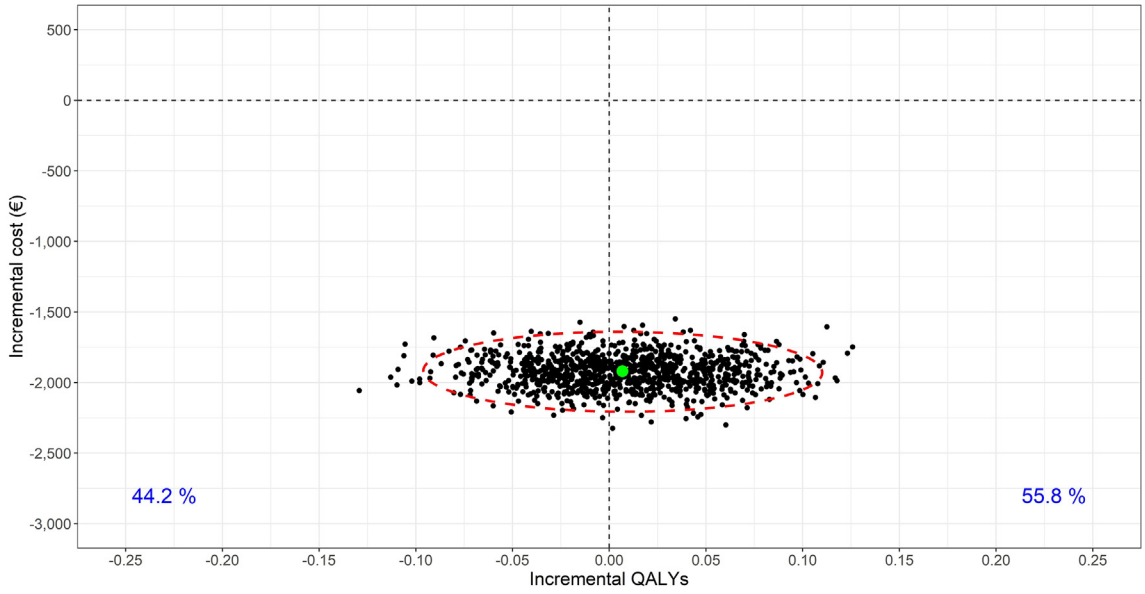

Fig. 1. Cost effectiveness plane and uncertainty analysis depicting the joint distribution of the difference in costs and QALYs beteween ABPI and WPI (reference strategy). The green dot indicates the point estimate of the incremental cost effectiveness ratio in costs per QALY.

Table 3
Budget impact analysis of implementing of the APBI strategy in all French radiotherapy departments in 2023.

	Year 2023
Annual number of new cases of breast cancer	59,135
Total targeted population†	15,240
WBI only (strategy 1)	
Total radiation therapy cost	€66,005,189
WBI with implementation of APBI (strategy 2)	
Implementation rate	100%
Total radiation therapy cost	€36,103,560
Cost difference between strategy 1 and 2	€29,901,629

† postmenopausal women with early-stage breast cancer.

cost-effectiveness plane for as-treated patients is presented in Supplement Figure 1.

National budget impact in France

Cost of radiation therapy for standard WBI, hypofractionated WBI and APBI were €5,692, €3,262 and €2,369, respectively. In a context of cost comparison between different radiation therapies for postmenopausal women with breast cancer at low risk of local recurrence, the implementation of APBI in all French radiotherapy departments would result in a 30 m€ (66 m€ versus 36 m€total saving per year of compared to the exclusive use of WBI (Table 3).

Discussion

To our knowledge, this is the first economic evaluation conducted on women with breast cancer at low risk of local recurrence comparing ABPI (ten fractions delivered twice daily over one week) to standard external WBI (one fraction per day delivered five days per week over three or six weeks). We found APBI was associated with lower cost for patients and no difference in QALYs compared to WBI. The mean cost per patient was €2,549 with APBI compared to €4,468 with WBI, i.e., a mean saving of €1,919 per patient treated. Adding transportation costs and daily compensation for sick leave increased the mean saving to €3,006. For an average of 60,000 new cases of breast cancer diagnosed annually in France, and 15,000 eligible for treatment with ABPI, the substitution of ABPI to WBI would result in a 30 million € cost saving per year..

Our results are consistent with previously published articles in some aspects but divergent in terms of inclusion criteria, radiation therapy, valuation of care and health care system since all French residents are entitled to publicly financed health care.

Shah et al. [20] performed a cost-effectiveness analysis at 90 days of an external beam image guided APBI technique compared with hypofractionated WBI (with or without boost) in women aged 40 years or older. They found that the direct cost for hypofractionated WBI with and without a boost was $4,551 (€5,646) and $3,666 (€4,650), respectively, whereas the cost for APBI was $2,966 (€3,762). Indirect costs (including time lost and travel cost) for hypofractionated WBI with and without boost were $1,609 (€2,041) and $1,274 (€1,616), compared with $603 (€765) for APBI. APBI had no difference in outcome measured by QALYs, 0.230 QALY for APBI compared to 0.229 for hypofractionated WBI (with or without boost). These QALY figures at 90 days were higher than in our study (0.405 for APBI and 0.406 for WBI) and might be explained by the difference in the minimum age required at inclusion and the difference in perception on health states between countries. A simulation of the treatment costs of APBI and WBI (42.5 Gy in 16 fractions, along with a 10Gy boost in 5 fractions) at five years, performed by A. Harat et al. [21], showed that the average treatment cost with APBI was lower than for WBI (€2,791 vs €4,244) and had a non-statistical significance higher local control rate.

As a trial-based economic evaluation, this study provided unbiased and generalizable estimates of the relative effect of APBI compared to the Standard or hypofractionated WBI and an opportunity to produce reliable estimates of cost for an internationally relevant decision problem. The prospective collection of resource utilisation and quality of life to estimate resource utilisation is also a major strength of this study.

In terms of the limits of our study, only direct medical hospital and transport costs were included in the cost analysis, and this assumes that other out-of-hospital costs such as medication and follow-up visits did not differ between arms. Indirect costs such production losses were not included, which may have biased the

results in favor of the APBI arm that had the lower rehospitalization rate. The time horizon chosen for the economic evaluation is three years and we assumed that all significant events related to radiation therapy or breast cancer would be severe enough to result in hospitalization within three years. It is likely that a longer follow-up would have provided additional useful information on long-term clinical and economic outcomes. However, the main cost driver is the radiation therapy delivered at the start of the follow-up period.

Finally, whilst missing data was imputed with MICE, QALY results may have been partially limited by the high proportion of missing utility scores after six months of follow-up (between 25% and 45%), and the annual questionnaires may not have captured quality of life during relapses, which may have led to an overestimation of quality of life.

As evidence for the delivery of radiotherapy for breast cancer patients is increasing, further reductions in treatment burden to patients and cost to the health care system can be expected with the uptake of new schedules. This however needs to be reconciled with the diagnosis related group-based (DRG) payment system, and the incentives to hospitals.

APBI is cheaper than WBI for the health insurance but results in revenue losses for hospitals.

Fast-Forward does not reduce costs to the health insurance compared to APBI, since the daily fee for radiotherapy treatment sessions is independent of the number of fractions performed.

It is necessary to better align the interests of both the healthcare system and the hospitals. Moving away from the DRG system to a novel bundled payment could allow speedier uptake of innovations such as teleradiotherapy, tumour board for particle treatment, tumor motion tracking. Bundled payments encourage cross financing of better equipment and isotopes through reduction in hospital admissions and transportation costs [22]. The rapid technological changes in the field of radiotherapy make it a ideal candidate for such financial experiments. The French general accounting office (Cour des comptes) recently pointed that the current payment system was outdated and did not serve the patients. A new payment model, based upon five bundles which are defined by technology but not by equipment or number of sessions is currently being tested (Sécurité sociale 2022 (ccomptes.fr).

Conclusion

The cost of radiation therapy, an essential component of expenditures for breast cancer treatment increases with the number of fractions administered and the duration of the treatment. The hypofractionated treatments are opportunities to considerably reduce the duration of treatments, treatment burden, and the number of hospital stays. They allow a better use of hospital resources without reducing the chances of cure in selected patients with favourable prognosis. APBI is increasingly being studied as a viable alternative to the standard radiotherapy. In this context, our study showed that amongst postmenopausal women with breast cancer at low risk of local recurrence, the economic evaluation favored APBI strategy, which reduced by 45% the cost of radiotherapy with no difference in outcome measured by QALYs.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.radonc.2023.109818.

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