Insurance Coverage for Adjuvant Proton Therapy in the Definitive Treatment of Breast Cancer

William M. Mendenhall, MD1; Stephanie Smith1; Christopher G. Morris, MS1; Julie A. Bradley, MD1; Raymond B. Mailhot Vega, MD, MPH1; Kathy McIntyre1; Stuart L. Klein, MHA1; Nancy P. Mendenhall, MD1

1University of Florida Health Proton Therapy Institute, Jacksonville, FL, USA

Abstract

Purpose: To determine factors that influence insurance approval for breast cancer patients for whom adjuvant proton therapy (PT) is recommended.

Patients and Methods: We sought to identify factors associated with PT approval among 131 insured patients seen in consultation between 2014 and 2018 and recommended adjuvant PT. Insurance status included: commercial, 76 patients (58%); Medicare, 41 (31%); and Medicaid, 14 (11%). Ninety-six patients (73%) had policies that “covered” PT. Insurance “coverage” for PT was not associated with final approval nor was lack of “coverage” associated with denial despite additional steps of medical review, peer-to-peer discussion, patient appeal, and judicial review.

In seeking approval, the following steps were required: medical review, 73 patients (56%); comparative dosimetry, 34 patients (26%); peer-to-peer discussion, 20 patients (15%); and administrative law judge, 1 patient (1%). A multivariate analysis of predictors for final insurance approval was conducted including the following covariates: T stage (Tis-T2 vs T3-T4); N stage (N0 vs N1-N3); laterality (left or bilateral vs right); insurance type (commercial vs Medicare/Medicaid) combined with potential insurance coverage (covered vs not covered); time period (2014-2016 vs 2017-2018); and age (<57 years vs 57 and older).

Results: Insurance approval was obtained for 93/96 patients (97%) with insurance that covered PT versus 23/35 patients (66%) whose insurance did not cover PT. Insurance approval stratified by insurance type and coverage was: commercial-covered, 52/52 patients (100%); Medicare or Medicaid-covered, 41/44 (93%); commercial-not covered, 16/22 (73%); and Medicare or Medicaid-not covered, 7/13 (54%).

On multivariate analysis, factors impacting approval revealed T stage, p=0.3127; N stage, p=0.8524; laterality, p=0.1829; insurance type combined with potential coverage, p<0.0001; time period, p=0.2731; and age, p=0.6678.

Conclusion: The only parameter that significantly influenced approval for treatment with PT was insurance type combined with potential coverage with ultimate approval rates ranging from 54% to 100%.

Keywords: Insurance, Proton Therapy, Breast Cancer
Introduction

Adjuvant radiotherapy (RT) is an integral component in the definitive treatment of patients with breast cancer. Depending on the location and extent of the malignancy, it may improve local-regional control and survival [1, 2]. Because of its proximity to the chest wall, the heart may receive a variable amount of irradiation which may, in turn, adversely impact long-term survival [3, 4]. The cardiac dose will depend on numerous factors including the target volume, breast cancer laterality, individual patient anatomy, and RT technique. RT injury to some parts of the heart, such as the left anterior descending coronary artery, may be more significant than to others.

Conventional RT techniques may include 3-dimensional conformal RT with or without electrons and with or without deep-inspiration breath-hold and intensity-modulated RT. Proton therapy (PT) may be used in lieu of conventional RT techniques to reduce the heart dose in some patients, thus reducing the likelihood of long-term cardiac morbidity and mortality [5, 6]. In some cases, PT is used to reduce exposure of lung tissue or to improve radiation coverage of the breast cancer target. The disadvantages of PT are that it is not widely available, and it is more expensive because more resources are required to build and operate a PT facility. The increased cost of PT may incentivize insurance companies to deny coverage [7, 8]. An additional issue is that the time required to obtain insurance authorization may be excessive, placing the patient in an uncomfortable race against the clock to begin radiotherapy before the cancer progresses and thus reducing the odds of a favorable outcome [8]. Some have proposed reimbursing PT at the same rates as for conventional RT (index pricing). One problem with this strategy is that reimbursement for conventional RT varies widely and, in some instances, may be higher than for PT in other locations. Another problem is the significant variation in how PT facilities are financed—some through municipal bonds, some through for-profit investment companies, some through federal or state grants, and some through philanthropy—making index pricing fair and reasonable for some entities and untenable for others.

The goal of this paper is to determine what factors might have influenced ultimate insurance approval for PT treatment in a series of patients seen at the University of Florida Health Proton Therapy Institute (UFHPTI; Jacksonville, FL).

Materials and Methods

We sought to identify factors associated with PT approval among 131 insured patients seen in consultation between April 2014 and November 2018 and recommended adjuvant PT. We performed a retrospective review of clinical and insurance information.

131 insured patients with breast cancer were seen in consultation at UFHPTI and adjuvant PT was recommended as part of their definitive treatment. Patient selection was based on extent of disease and patient anatomy such that the use of PT would likely significantly reduce radiation exposure to organs at risk including the heart and lungs. Patients who received prior irradiation to all or part of the target volume were excluded. Patients were consented to participate in an institutional review board-approved outcomes tracking protocol. Additionally, some patients were offered the opportunity to participate in 1 of 3 clinical trials. Patients thought to be at risk for internal mammary lymph node metastases based on laterality, primary site, and extent of disease routinely had these lymph nodes included in the target volume. The median age was 57 years (range, 26 to 86 years). The patient population is depicted in Table 1.

Insurance status included commercial, 76 patients (58%); Medicare, 41 patients (31%); and Medicaid, 14 patients (11%). Ninety-six patients (73%) had insurance plans that “potentially covered” PT, meaning that the policy stated it would reimburse PT treatments. Some insurance companies that did not “cover” proton therapy occasionally approved and paid for treatment with PT. With or without “coverage,” a lengthy process of medical review and decision appeal might ensue before a final decision was made to approve or not approve treatment with PT. Ultimate insurance approval to treat was the endpoint of this study.

Typically, if the request for approval is denied, there is a first-level appeal, a second-level appeal, and then an external review, if offered by the plan. Comparative dosimetry, if requested, usually is obtained early in the process. A final appeal may be to an administrative law judge.

JMP Pro Version 14.0.0 was utilized for statistical analysis (SAS Institute, Cary, NC). Multiple logistic regression of the binary approval endpoint included the following prognostic factors: T stage (Tis-T2 vs T3-T4), N stage (N0 vs N1-N3), laterality (left or bilateral vs right), insurance type (commercial vs Medicare/Medicaid), time period (2014-2016 vs 2017-2018), insurance coverage (covered vs not covered), and age (<57 years versus 57 years or older).
Results

Two patients (2%) had insurance that required consultation prior to consideration of approval for PT. A peer-to-peer was required for 20 patients (15%), not required for 110 patients (84%), and no data was available for 1 patient (1%). An expedited review occurred for 18 patients (14%), did not occur for 112 patients (85%), and no data was available for 1 patient (1%). A medical review was required for 73 patients (56%), was not required for 57 patients (43%), and no data was available for 1 patient (1%). Dosimetric treatment plans comparing PT and conventional RT were required for 34 patients (26%) and not required for 97 patients (74%). An appeal to an administrative law judge occurred for 1 patient (1%), did not occur for 129 patients (98%), and no data was available for 1 patient (1%). The number of appeals were: none, 114 patients (87%); 1, 11 patients (8%); 2 or more, 5 patients (4%); and no data, 1 patient (1%).

Ninety-six patients (73%) had insurance that would potentially cover PT. Approval for PT was obtained in 93 patients (97%) with insurance that potentially covered PT. The 3 patients whose insurance potentially covered PT did not have a Medicare/Medicaid HMO product. Although 35 patients had insurance that did not cover PT, approval was ultimately gained in 23 (66%). Insurance approval for treatment with PT stratified by insurance type and coverage is shown in Table 2. Overall, 116 patients (89%) were approved for treatment with PT.

Univariate analysis revealed the following: T stage, \( p = 0.3001 \); N stage, \( p = 0.3831 \); laterality, \( p = 0.1622 \); insurance status, \( p = 0.2679 \); potential insurance coverage, \( p < 0.0001 \); time period, \( p = 5895 \); and age, \( p = 0.4183 \). Because type of insurance and coverage were significantly associated with insurance approval, multivariate analysis was performed to determine the independent association between these variables and approval for treatment with PT.

| Parameter                  | Patient Number (%) |
|----------------------------|--------------------|
| T stage                    |                    |
| Tis                        | 1 (1%)             |
| T1                         | 62 (47%)           |
| T2                         | 45 (35%)           |
| T3                         | 16 (12%)           |
| T4                         | 7 (5%)             |
| N stage                    |                    |
| N0                         | 43 (33%)           |
| N1                         | 66 (51%)           |
| N2                         | 11 (8%)            |
| N3                         | 11 (8%)            |
| Laterality                 |                    |
| Left                       | 105 (80%)          |
| Right                      | 26 (20%)           |
| Adjuvant chemotherapy      |                    |
| Yes                        | 97 (74%)           |
| No                         | 32 (24%)           |
| No data                    | 2 (2%)             |
| Adjuvant hormonal manipulation |                |
| Yes                        | 72 (55%)           |
| No                         | 54 (41%)           |
| No data                    | 5 (4%)             |

*4 patients (3%) with bilateral breast cancers were staged according to the more advanced side.

Table 1. Patient population (131 patients).

| Insurance Type and Coverage | Insurance Approval |
|-----------------------------|--------------------|
| Commercial-covered          | 52/52 patients (100%) |
| Medicare/Medicaid-covered   | 41/44 patients (93%)  |
| Commercial-not covered      | 16/22 patients (73%)  |
| Medicare/Medicaid-not covered | 7/13 patients (54%)  |
| Total                       | 116/131 patients (89%) |

Table 2. Insurance approval for treatment with proton therapy depending on insurance type and coverage.
potential coverage appeared to be related, they were combined into one variable for the multivariate analysis. Multivariate analysis revealed the following: T stage, $p = 0.3127$; N stage, $p = 0.8524$; laterality, $p = 0.1829$; insurance type combined with potential coverage, $p < 0.0001$; time period, $p = 0.2731$; and age, $p = 0.6678$.

Treatment that was eventually delivered included UFHPTI protons, 99 patients (76%); UFHPTI protons with a photon boost, 18 patients (14%); UFHPTI photons, 10 patients (8%); treatment elsewhere, 2 patients (2%); and no treatment, 2 patients (2%). Some patients who did not receive insurance approval for PT were treated as financial hardship with PT, as were some uninsured patients not included in this study.

**Discussion**

There are few data evaluating insurance approval for cancer treatment with PT; however, our findings align with those determined by Gupta et al. who similarly demonstrated that PT coverage was associated with insurance category only on multivariable analysis [8]. It is likely that this endpoint varies with the country in question and medical resources available. Insurance companies in the United States have been more likely to approve PT for uncommon malignancies, such as pediatric cancers, uveal melanomas, and hepatocellular carcinomas, as well as some where the likelihood of cure is low and the risk of severe complications is high such as re-irradiation for head and neck cancer. In general, there has been more resistance to treating patients with more common malignancies such as human papilloma virus-positive oropharyngeal squamous cell carcinomas, breast cancers, and prostate cancers. Many take it for granted that PT is clearly better for many pediatric malignancies when, in fact, the data supporting that contention are no more compelling than for many adult cancers.

Our data show that patients seen in consultation for breast cancer where PT was recommended were usually ultimately approved for treatment. Most required a medical review and a substantial proportion required a comparison plan and/or a peer-to-peer discussion, which potentially delays the initiation of PT. Even so, comparison plans have been negatively associated with PT approval [7]. The only factor that significantly impacted insurance approval for treatment with PT was insurance type combined with potential coverage.

Limitations of our study include our unavoidable inability to identify patients who might have benefitted from PT but were not referred because they lacked insurance or insurance coverage for PT, and it was deemed unlikely that their insurance would ultimately approve PT. Another limitation is the regrettable lack of data related to the time required to secure a final decision regarding insurance approval. Other series have noted such delays to span an average of 3 weeks and up to 4 months [8]. An additional limitation is that we do not have data pertaining to the potential participation in a clinical trial and its impact on insurance approval.

In conclusion, most patients evaluated at our center where adjuvant PT for breast cancer was recommended received insurance approval. Some who did not still received PT through self-pay or charity programs. The only factor that significantly impacted insurance approval for treatment with PT was insurance type combined with potential coverage. An obvious problem is that many patients have no idea whether their insurance potentially covers PT and do not find out until after they are diagnosed with cancer.
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