



**Patient-Reported and Toxicity  
Results from the FABREC Study:  
A Multicenter Randomized Trial  
of Hypofractionated vs.  
Conventionally-Fractionated  
Postmastectomy Radiation  
Therapy after Implant-Based  
Reconstruction**



*Presented by:*

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# Disclosure & Study Team

- I have no conflicts of interest to disclose
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# Background

- Postmastectomy RT indicated for ~30% of mastectomy patients
- Immediate reconstruction at time of mastectomy has benefits
- Implant-based reconstruction with tissue expander or implant
- Radiation (5-6 weeks) increases risk of reconstruction complications
- Hypofractionation (3-4 weeks) has been widely adopted after breast-conserving surgery
  - Equivalent long-term oncologic and improved 6-month quality of life (QOL) outcomes
  - Improved cosmetic results

# Patient experiences with CF

Patient 1	The <b>hardest thing about radiation was the time it took to do it</b> and scheduling.
Patient 2	I live far so coming in for daily radiation for over 5 weeks meant missing significant life events. I missed my kids' first day of school. I had to get a friend to do my daughter's hair because I missed picture day. I would have definitely wanted short-course radiation had it been an option. It's time you don't get back.
Patient 3	I stayed in Boston every other night so that I was just driving two hours a day instead of four. This meant that I was away from the kids every other day. I couldn't afford a hotel. Five weeks of treatment was a huge strain on me and my family. I would be thrilled if there were new methods created where future working mothers like me wouldn't have to miss over a month of their family's lives. I was lucky to find free places to stay, but it was a financial strain on us to have me traveling, paying for gas, and eating out when I was away. If I hadn't found free housing, I wouldn't have been able to stay in Boston and then all that driving would have impacted my job, which would have major life implications. By week three of treatment, I started to feel very down. I was alone, the novelty had worn off, I was sad and felt like it would never end. <b>With so many treatments, by the last two weeks I do think I was developing some level of anxiety and (radiation) machine phobia.</b>
Patient 4	I like the idea of taking the radiation down to 3 weeks...anything to reduce the time is great.
Patient 5	My mother had breast cancer at the same time as me and was able to have a radiation regimen that lasted only 3 weeks...but for me (because of the mastectomy and reconstruction) it wasn't possible.

# Methods

- 400 patients with Stage 0-III breast cancer treated with mastectomy and immediate implant-based reconstruction
- Enrolled between 3/2018 and 11/2021 across 16 institutions
- Randomized 1:1
  - Conventional Fractionation (CF):
    - 25 fractions (M-F, 5 weeks) of 200 cGy
  - Hypofractionation (HF):
    - 16 fractions (M-F, ~3 weeks) of 266 cGy
- Primary study endpoint was improvement in the Physical Well-Being ( $\Delta$ PWB) domain of FACT-B at 6 months controlling for age

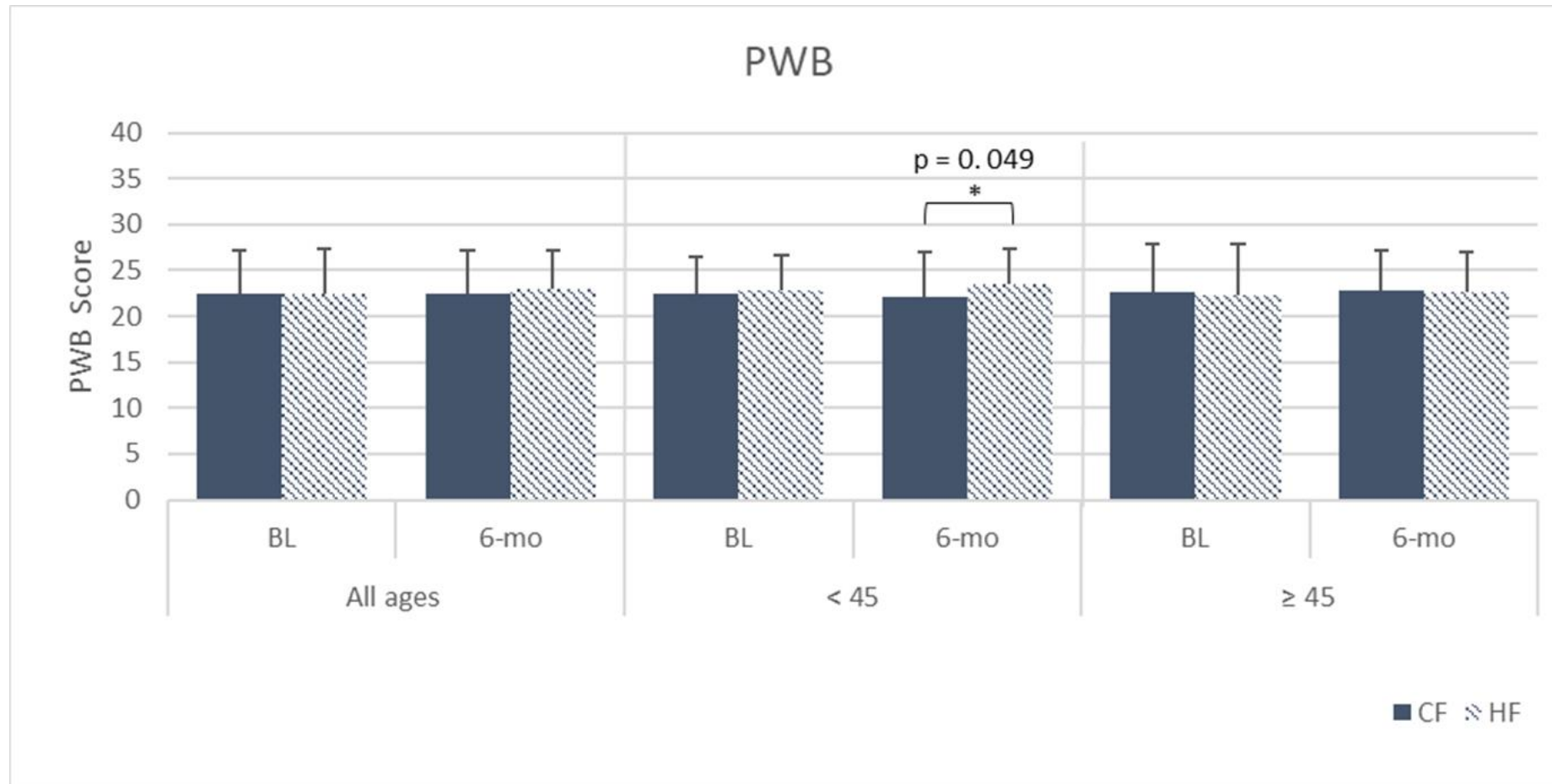
# Study cohort

- Randomization: 201 CF and 199 HF arm
- Median age 47.0 years (range, 23-79)
- Median time from surgery to PMRT was 2.6 months
- Treatment break
  - 7.7% in CF (average 3.3 days)
  - 2.7% in HF (average 2.8 days)
  - $p=0.03$

# Results – HF versus CF

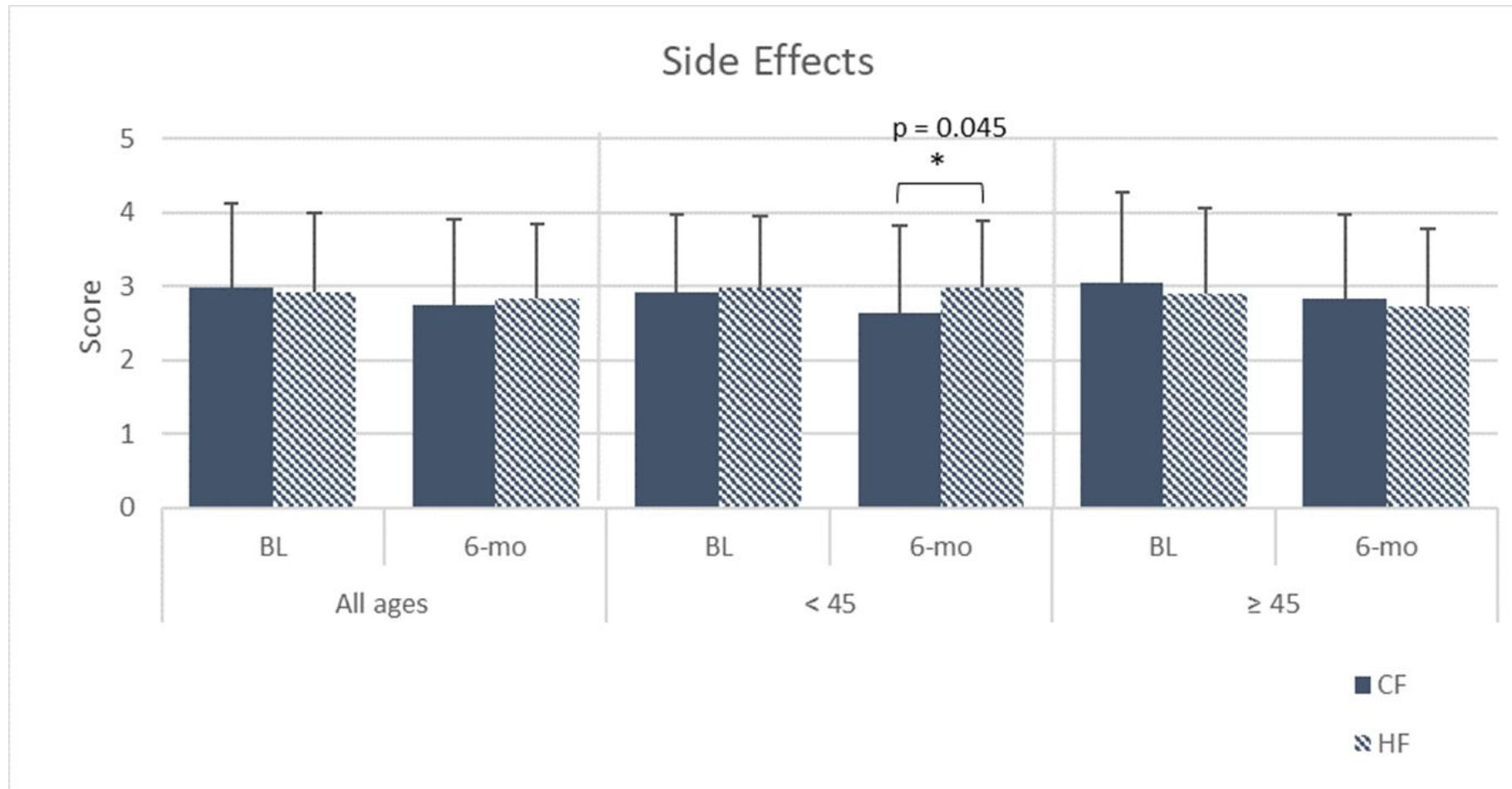
- 385 patients analyzed with median f/u of 40.4 months
- No difference in any of the oncologic outcomes
  - Distant recurrence, Death, Local Recurrence
- No difference in toxicity outcomes
  - Chest wall toxicity (p=0.80)
    - 39 patients (19 CF; 20 HF)
- Change in Physical Well Being ( $\Delta$ PWB) score at 6-months controlling for age group (<45 versus  $\geq$ 45 years)
  - $\Delta$ PWB = 0.20 (95% CI:-0.80,1.18) with HF (p=0.70)

# Results - Physical Well-Being





# Results – Less bothered by side effects



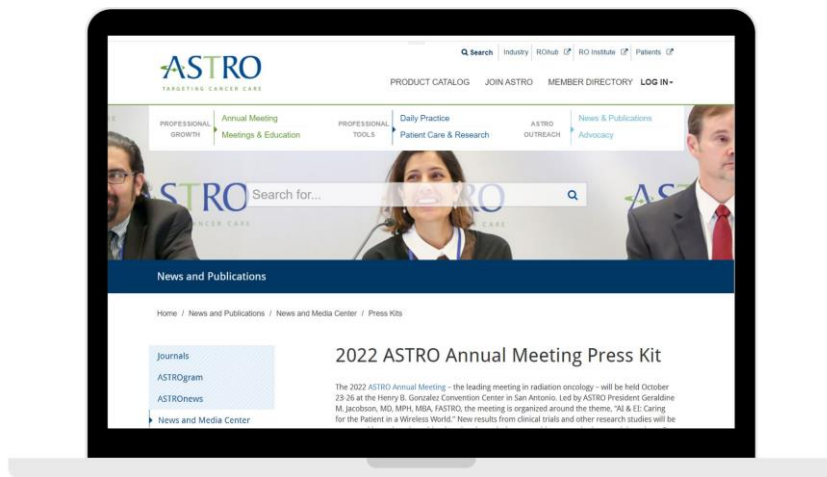
# Results – Financial toxicity

- Mean number of hours of unpaid time off from work for treatment among those patients who took such time (n=51)
  - 125.8 hours for CF
  - 73.7 hours for HF
  - $p=0.046$

# Conclusions

- First study to report randomized phase III results of HF vs. CF in patients with mastectomy and implant-based reconstruction
- Primary outcome and toxicity profile of HF comparable to CF
- Improvement in specific QOL domains with HF, especially among younger patients
- Fewer treatment breaks with HF
- Less financial toxicity with HF
- Our results support the use of HF PMRT for patients with implant-based reconstruction

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