

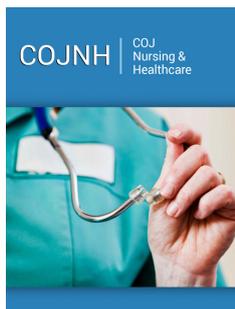
Improving Fulvestrant Intramuscular Injection Waiting Time for Advanced Breast Cancer Patients at Johns Hopkins Aramco Healthcare-Rapid Quality Improvement Initiative

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Abstract

Introduction:Fulvestrant is an estrogen receptor (ER) antagonist commonly used to treat advanced or metastatic breast cancer in postmenopausal women with hormone receptor positive. It is administered as a 1 to 2 minutes intramuscular injection designed as a solution in pre-filled syringe. Merely, placing a stock of injection medication within the ambulatory oncology clinic leans the process and makes it safer and more convenient to patient and healthcare providers. This is a quality improvement initiative; a rapid quality management PDCA cycle methodology was used. The main goal is to reduce the Fulvestrant injection wait time for Breast cancer patients by at least 60% in 3 months.

Methods and materials:Fulvestrant injections were made as a “Pyxis” item, and few doses were kept in oncology fridge to be refilled as needed and the stock is monitored. A total of 50 breast cancer cases were included in the baseline data pre-action plan implementation, a parallel number was used for post-change data analysis.

Results: Data analysis revealed that Breast cancer patient wait time reduced from 59 to 14 minutes. Ultimately, this achievement significantly reflected an increased patient satisfaction from 15% to 93% (p=0.000).

Conclusion:Certainly, inventing quality of an efficient and safe healthcare in a timely manner has clearly led to sufficient utilization of the oncology treatment rooms that accordingly has affected the patient’s satisfaction level positively.

Keywords: Fulvestrant; PDCA cycle;Efficient and safe healthcare;Patient satisfaction

Introduction

The common approaches to treat advanced or metastatic breast cancer in postmenopausal women, which are hormone-responsive tumors with progression, is relying on hindering Estrogen from binding to its estrogen receptor (ER). This is achieved by either using an anti-estrogen or reducing estrogen levels using an inhibitor [1]. Tamoxifen is an ER modulator that is broadly used hormonal treatment for breast cancer, and it is highly effective in reducing the incidence rate in high-risk patient [2], however, some patients develop resistance to it. Numerous pre-clinical studies indicated that “Livestrong” would be effective in tamoxifen-resistant breast cancer [1,3]. Fulvestrant (Faslodex) is an antineoplastic specific estrogen receptor (ER) antagonist with a steroidal novel action mode as it blocks and surges degradation of ER and thus downregulation, with no known agonist effects [4,5]. As well, when it binds to the ER it leads to a rapid loss of ER protein in the tumor ensues [4]. Consequently, this effect will result in significant reduction of tumor progesterone receptor (PgR) levels 1 therefore breast cancer suppression. Taking into consideration all the required precautions as per Food and Drug Administration (FDA) standards and other clinical guidelines, including no allergy to Fulvestrant or its ingredients. It is administered as a 1 to 2 minutes intramuscular long-acting compound for injection at the gluteal area [6].

It is designed as a 250mg/5ml solution for injection in pre-filled syringe, with no further drug concentration needed because of its low suability, which has a proven chemical-

pharmaceutical quality with favorable efficacy and safety profile [7,8]. In some healthcare setting, Fulvestrant doses are located within the cancer center as one of stock items related to oncology list. Other setting might have this drug placed in the pharmacy department and releases whenever ordered by oncology center. Simply, having an injection medicine situated within the serving site, for instance ambulatory oncology clinic, makes the healthcare process safer and more convenient to patient and health care providers.

Methods and Materials

This study conducted in an outpatient oncology institute at Johns Hopkins Aramco Healthcare (JHAH); tertiary hospital located in Kingdom of Saudi Arabia. An Ethical approval was obtained from the Institutional Review Board to publish the quality outcome of this project. This quality improvement initiative was among a list of other quality efforts to improve the service for oncology patients at JHAH. A rapid four steps quality management method; Deming PDCA cycle, was used to execute this project. The main goal is to reduce the Fulvestrant injection wait time for advanced Breast cancer patients by at least 60% in 3 months, in order to have a process that is convenient for patients and staff. This will eventually enhance patient satisfaction and mend the efficiency at oncology clinic granting sufficient use of treatment rooms. The plan (P) was to lean the process of getting, verifying and

administering the Fulvestrant IM injection to Breast cancer patient in a safe and timely manner. Originally, the Fulvestrant injection was placed within the pharmacy and the order needs to be verified by pharmacist, approved, released then sent to oncology. To do (D) the proper intervention, the Fulvestrant injection was made as a "Pyxis" item, and few doses were kept in oncology fridge to be refilled as needed and the stock is monitored. Data collected after changing the practice to check (C) the performance improvement. A statistical t-Test was used to calculate the significance of the improvement. Once a progress is confirmed we acted on adjusting (A) the previous exercise accordingly.

Result

Fulvestrant Intramuscular (IM) injection Key performance indicator (KPI): This KPI defined as time from "releasing the order in Epic system" to "complete IM injection administration". A total of 50 breast cancer cases collected for baseline data (from July to September 2018), revealed that patients wait at the oncology treatment room for almost an hour (59 minutes) to receive their Fulvestrant IM injection. Similar number of cases post implementation of action plan data collected (from October to December) showed a dramatic reduction to 14.7 minutes, with a P value ≤ 0.001 (95% Confidence Interval of 9.8 -21 minutes), with 75% improvement and time saving (Figure 1).

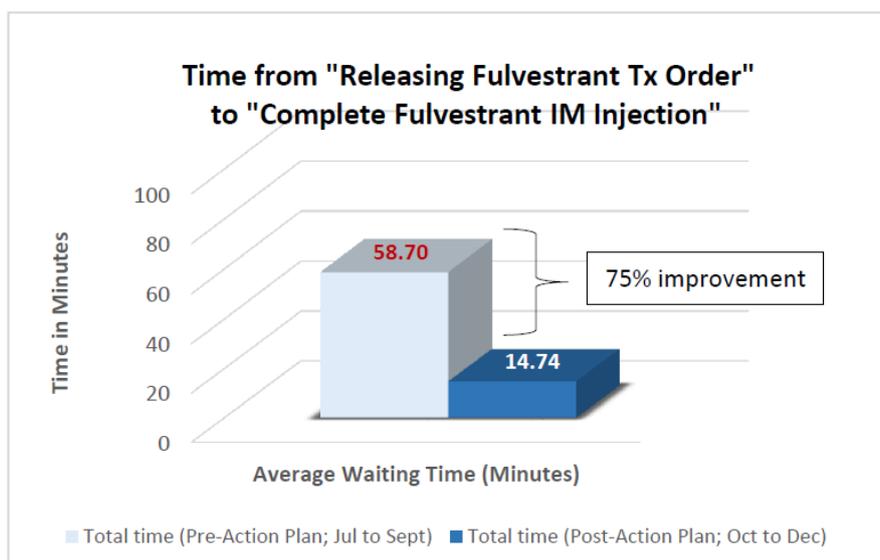


Figure 1: Bar graph displays the significant reduction in Fulvestrant IM injection waiting time after implementing the new practice.

Oncology Patients Satisfaction Rate: This simple quality improvement initiative was reflected on the patient's "Waiting time at oncology clinic" satisfaction rate. It was significantly elevated from 15% (for 3 months pre-implementation of action plan) to 93% (for 3 months post-implementation) with an obvious significant improvement ($p \leq 0.000$). This was indicated by patient's comments

collected through the monthly "Press Ganey" survey (Figure 2). Moreover, personal interview with oncology patients who received Fulvestrant treatment conducted to ensure the level of satisfaction before and after changing the process. Outcome analysis results confirmed patient satisfaction with the new practice and for spending a less time for an injection ($P = 0.0004$) (Figure 3).

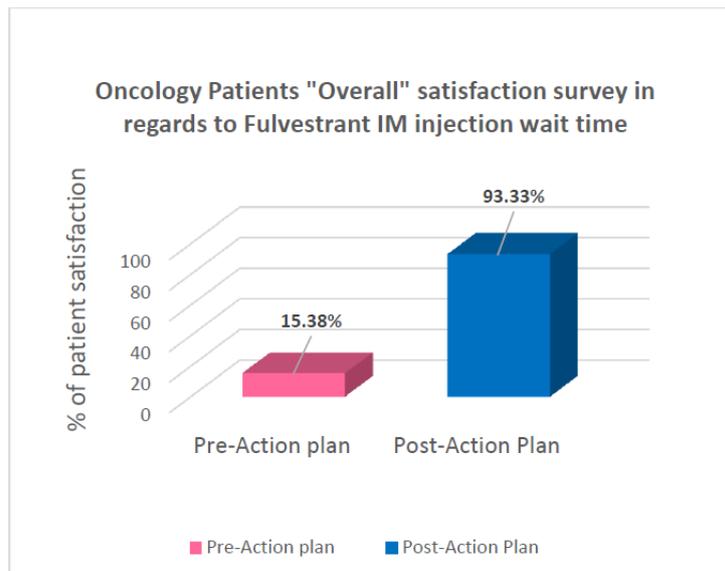


Figure 2: Bar graph shows the significant elevation in patient satisfaction rate after changing the protocol.

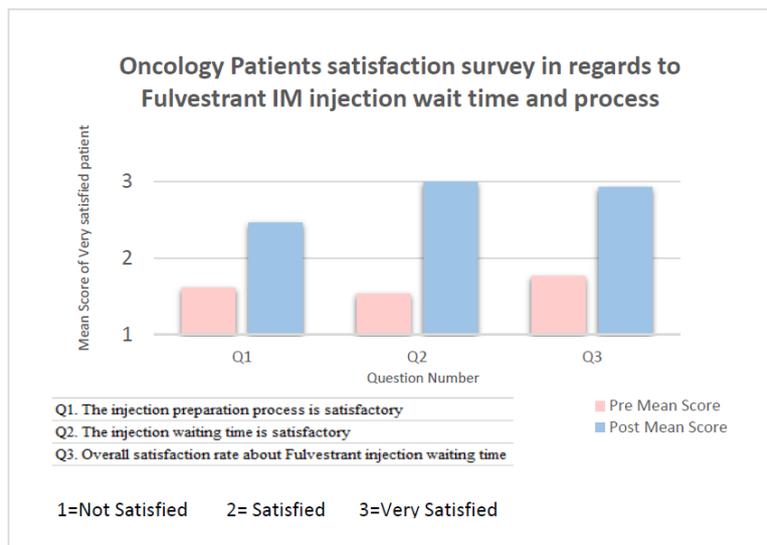


Figure 3: Bar graph illustrates the satisfaction score in relation to questionnaire-concerned points.

Discussion

Breast cancer incidence ranks first amongst other women malignancies worldwide with topmost mortality rates [9]. Fulvestrant is the anti-estrogen commonly used in clinical practice. It is the core stone of estrogen receptor (ER) pathway driven breast cancer and advanced breast cancer in postmenopausal women, as well as for hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2) naïve patients. Several clinical studies showed its significant effect yielding to longer progression-free survival (PFS) compared to other treatments [10]. Fulvestrant commercially known as Faslodex should be administered intramuscularly, slowly, and within 1-2 minutes per injection [11]. In our organization at JHAH, this injection is kept within pharmacy

department that needs to be ordered, approved and transported to oncology treatment unit. The process takes almost an hour (59 minutes) to administer the Fulvestrant IM injection to the patients. A rapid quality improvement initiative has been conducted to reduce the patient wait time for an IM injection. The post-action plan data revealed a 75% reduction in waiting time reached 14.7 minutes. In addition, this simple quality improvement project reflected an increase in patient’s satisfaction rate (from 15% to 93%) towards the “Waiting time at oncology clinic”, as indicated by the monthly “Press Ganey” survey results. Nevertheless, a reactive initiative was conducted through personal interview with breast cancer patients who received Fulvestrant treatment, seeking a feedback about the process changes. The analysis confirmed patient contentment

with the new practice with a significant less time for an injection ($P=0.0004$).

Conclusion

In conclusion, the implemented action plan has proven to improve the Fulvestrant IM injection wait time for advanced Breast cancer patients considerably. Such improvement has also led to sufficient utilization of the oncology treatment rooms, which increased the number of served patients during the day. Certainly, inventing quality of an efficient and safe healthcare in a timely manner has clearly affected the patient's satisfaction level positively.

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