Impact of Specialty Pharmacies on Stomatitis Prophylaxis with Dexamethasone at Everolimus Therapy Initiation

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Background

2017 SWISH trial concluded that prophylactic use of dexamethasone mouthwash reduced the incidence and severity of stomatitis of patients on Everolimus (Afinitor®). Thereafter everolimus prescribing information was updated to include use of dexamethasone at everolimus initiation. Specialty pharmacies (SPs) are in a unique position to ensure patients start therapy appropriately to reduce adverse events, increase adherence, and improve outcomes.

Objective

Observe the impact of specialty pharmacies on improving outcomes and quality of care for patients via access to dexamethasone upon initiating everolimus.

Methods

- Retrospective observation of data within TherigySTM® clinical management platform between July 2018 to April 2020 of selected SPs where patients (n=206) were screened for mouthwash prescription at everolimus initiation.
- TherigySTM® prompted users to screen for mouthwash upon patient onboarding and clinical assessments.
- If mouthwash script is negative, resources on the benefits and a link to a free voucher for dexamethasone was provided.
- Negative statuses were compared upon subsequent clinical follow-ups to track change.
- Data was collected via TherigyInsights™ and odds ratio (OR) analysis performed using Microsoft Excel®.

Results

- A total of 102(49.5%) patients reported “yes” to script versus 117(56.8%) on the last observable follow-up
- In pts with ≥2 responses (n=22), 15(68.2%) reported a positive change of “no” to “yes” for script.
- In pts with discontinuations (n=90), 11/28 (39.3%) with no dexamethasone ended ≤30 days versus 7/62 (11.3%) with dexamethasone; OR: 5.1 (95% CI 4.9- 5.3; p=0.003).

Conclusion

- Patients starting everolimus without dexamethasone showed a significantly higher chance of early therapy discontinuation and patients that initially did not have dexamethasone script had a 68.2% positive status change.
- The limitations of the study include data gaps such as incidence and severity, resolution of stomatitis, and valid reasons to a negative dexamethasone script.
- It is unclear that dexamethasone is solely responsible if a patient is likely to discontinue early. However, patients who ultimately reported access to dexamethasone can be viewed as a surrogate marker of success from services performed by SPs.
- SPs who are ensuring patients having a proper start of therapy are more likely to perform other services in maximizing patient’s outcomes. Future prospective studies would be needed to address the data gaps mentioned.

Sources:

AFINITOR (everolimus) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. 2020

Rugo HS, Seneviratne L, Beck JT, et al. Prevention of everolimus-related stomatitis in women with hormone receptor-positive, HER2-negative metastatic breast cancer using dexamethasone mouthwash (SWISH): a single-arm, phase 2 trial. Lancet Oncol. 2017;18(5):654-662. doi:10.1016/S1470-2045(17)30109-2

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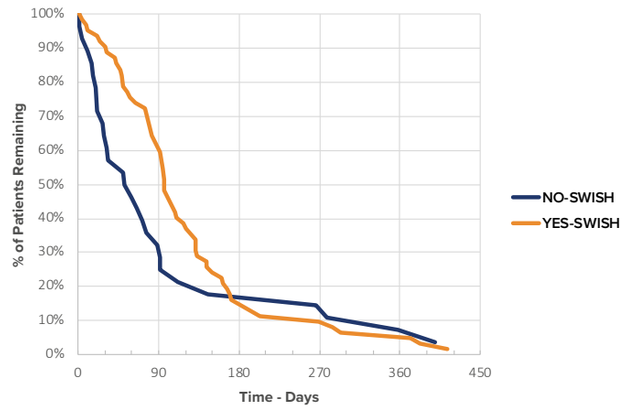
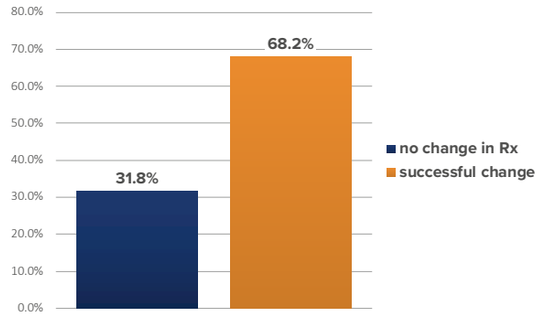
Time to Discontinuation Due to Any Clinical Reasons

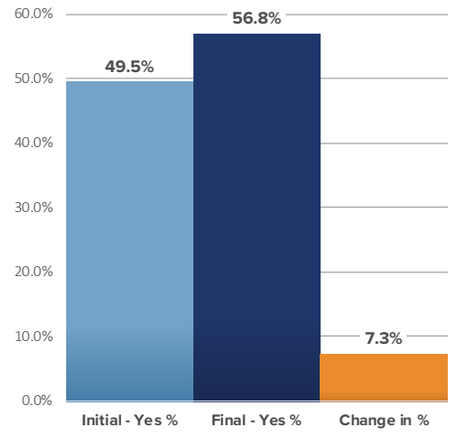


SWISH STATUS	Discontinued in 30 days or less
NO Dexamethasone Rx (n=28)	39%
YES Dexamethasone Rx (n=62)	11%

Dexamethasone Rx Status Change



Dexamethasone Rx at Baseline Comparison



Patient Demographics

206 Study Participants

180 Women | **103** Men

Most Prevalent Documented Diagnosis:
Advanced HR+, HER-2 Breast Cancer

169 New to AFINITOR
20 Existing AFINITOR Patients
17 AFINITOR Status Unknown

67%
Above the Age of 65