Assessing and modeling organizational impact of tilmanocept in sentinel lymph node in breast cancer and melanoma

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Background

Sentinel lymph node biopsy (SLNB) has already become a standard of care for breast cancer patients [1] and selected patients with melanoma [2]. However, this technique requires a specific organization including a strong collaboration among different departments within a hospital. Thanks to its molecular characteristics, including its rapid onset of action, its long duration of action and its rapid clearance, tilmanocept, a novel radiotracer indicated in SLNB, could allow hospitals to save time and therefore improve patients workflow especially for ambulatory activities.

Objective

The aim of this study was to build a model to assess the organizational impact of tilmanocept in the SLNB for breast cancer and melanoma in ambulatory setting.

Method

In order to know the care pathway related to the SLNB technique and to evaluate the impact of tilmanocept in current practice, 11 practitioners from each specialty concerned with sentinel node biopsy were interviewed:

- 4 nuclear physicians
- 2 radio-pharmacists
- 5 surgeons

Each interview was based on a specific validated guide regarding each specialization and divided into two parts:

The first part of which was designed to learn about their current practices (pathway, time) in the sentinel lymph node technique

The second part of the interview was then devoted to the potential impact that, according to them, tilmanocept could have on the organization in departments involved in the SLNB procedure such as radiopharmacy service, nuclear medicine service and operating room.

Prior to this one-hour interview, the characteristics of tilmanocept, as described within the Summary of Product Characteristics (SmPC), including its rapid onset of action, its prolonged localisation time within sentinel node, its rapid clearance and its efficacy from phase III clinical trial results were sent out for information.

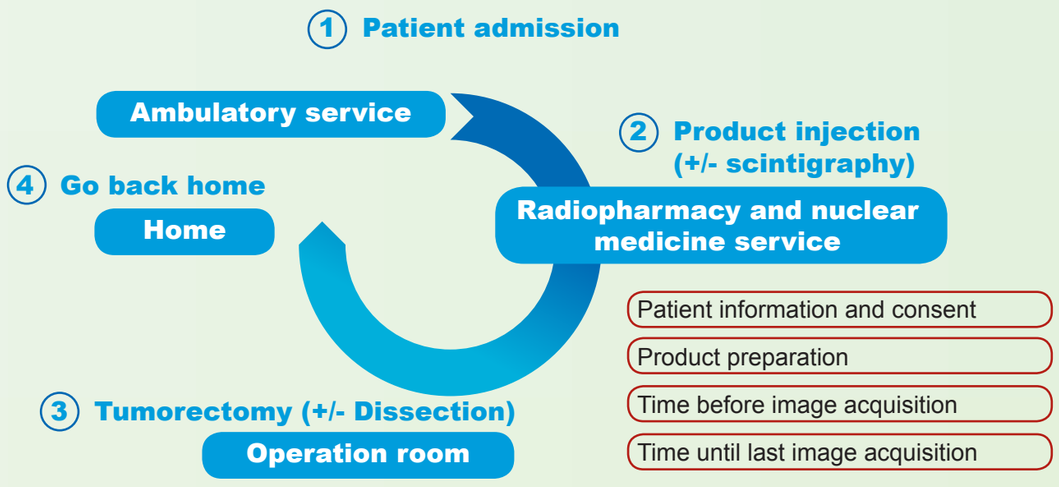
Information collected during the interviews was supplemented by a literature review and PMSI* data. Then an organizational model based on information collected was built.

Model and Inputs

The model considers the time spent to set up a SLNB service with different radiotracers in a cohort of patients undergoing SLNB procedure and calculates time-saving by tilmanocept compared to radiotracers currently used in hospital. The saved time by the cohort is translated into additional patients who could undergo SLNB in an ambulatory setting. The increase in ambulatory activity is then calculated.

The pathway of a patient undergoing SLNB procedure was modeled in 4 steps corresponding to each service involved in SLNB procedure. A schematic representation is shown in figure 1.

Figure 1: Model structure



In order to adapt to each hospital, the characteristics of each service (staff, opening day, time range, number of operating rooms) can be modified by user.

In accordance with the information contained in SmPC, we made the hypothesis that the preparation of one vial served for one patient.

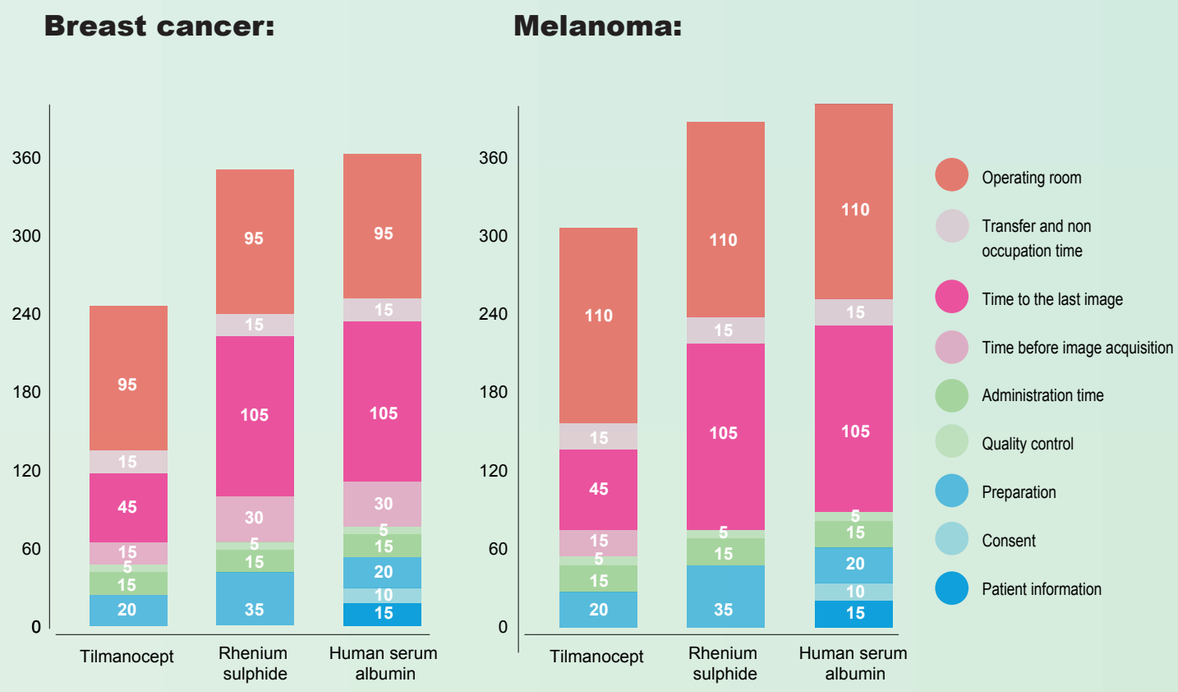
All steps performed in each service and their associated time based on SmPC, interviews and literature data are included in the model and can be changed and adapted according to hospital organization (figure 2).

Discussion

The model allows to simulate a cohort of patients undergoing SLNB and to see the impact of the introduction of tilmanocept. The model is extremely flexible to adapt to all hospitals but requires a lot of information that may be time consuming to input.

Further, the model does not simulate the path of patients undergoing detection and surgery in two different hospitals. Finally, the impact of tilmanocept's prolonged localisation time within sentinel node (up to 30 hours), which could have an impact on the pathway flexibility, is not modeled.

Figure 2: Lead times with different radiotracers for setting up a SLNB



Results

A hypothetic cohort of 30 patients with breast cancer and 20 patients with melanoma undergoing SLNB per week was entered in the model.

Total time saving per week in all indications for the entire cohort with Tilmanocept Vs		
Colloid	Time saving (min)	Time saving (hours)
Rhenium sulphide	2190	37
Human serum albumin	37	45

Among these patients, 9 (30%) patients with breast cancer and 3 (13%) patients with melanoma undergo SLNB in ambulatory setting. The table below shows time saving in ambulatory setting and potential ambulatory growth that it could be possible to have with tilmanocept.

In breast cancer:

Time saving and additional patients per week in Breast Cancer in ambulatory setting with Tilmanocept Vs			
Colloid	Time saving (min)	Potential additional patients	Ambulatory increase
Rhenium sulphide	5	2	22%
Human serum albumin	6	2	22%

In melanoma:

Time saving and additional patients per week in Melanoma in ambulatory setting with Tilmanocept Vs			
Colloid	Time saving (hours)	Potential additional patients	Ambulatory increase
Rhenium sulphide	3	1	38%
Human serum albumin	3	1	38%

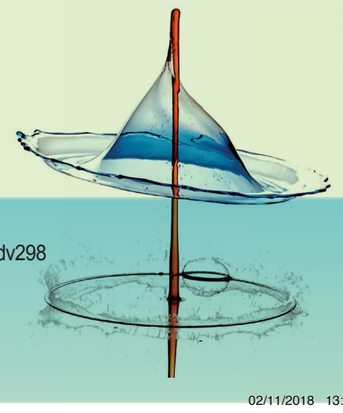
According to the comparators, tilmanocept could save between 37 and 45 hours per week for the entire cohort of patients undergoing SLNB.

In ambulatory setting, tilmanocept could save between 5 and 6 hours per week in breast cancer. The time saved can be converted into 2 additional patients per week eligible for SLNB for breast cancer which could represent an ambulatory growth of 22%.

For melanoma, tilmanocept could save 3 hours per week. The time saved can be converted into 1 additional patient per week eligible for SLNB for melanoma which could represent an ambulatory growth of 38%.

Conclusion

Tilmanocept could reduce the procedure times (preparation, administration, imaging) and therefore decrease time of procedure for all patients and increase ambulatory activity of the SLNB in breast cancer and melanoma.



* PMSI : Program of Information Systems Medicalization

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