Impact of Patient Blood Management (PBM) on the Reduction of Transfusion Requirements in Patients Undergoing Major Planned Orthopedic Surgery in Italy

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INTRODUCTION

Inappropriate Red Blood Cell (RBC) transfusion is associated with increased risk of mortality, infection, transfusion reaction, post-operative complications (such as circulatory overload, thromboembolic events), prolonged hospitalization (1, 2). Patient Blood Management (PBM) is a patient-centered approach that addresses iron deficiency, anemia, coagulopathy and blood loss, in surgical and nonsurgical patients, as risk factors for adverse medical outcomes (3). The systematic application of a PBM program in the hospital setting during the peri-operative period has been found to obtain better patient clinical outcomes following surgery (4, 5).

The objective of the current study was to compare RBC transfusion rates before vs. after PBM implementation in Humanitas Research Hospital of Milano, Italy.

METHODS

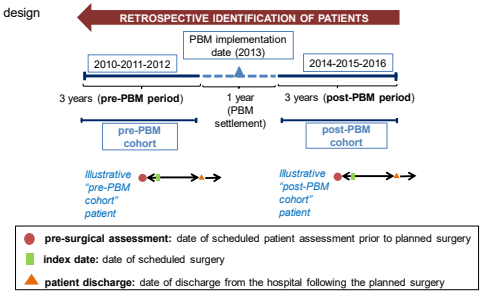
STUDY DESIGN. This is an observational retrospective study among adult patients who underwent major planned orthopedic surgeries (hip or knee replacement) in Humanitas Research Hospital of Milano, Italy.

STUDY POPULATION. Two separate cohorts:

- pre-PBM cohort: orthopedic surgeries performed during the 3 years period before PBM program use (2010 to 2012)
- post-PBM cohort: orthopedic surgeries performed during the 3 years period after PBM implementation (2014 to 2016)

STUDY COLLECTION PERIODS. The date of the patient surgery was referred to as **index date**. The data collection period spanned two main stages anchored to the date of index event: the **pre-surgical assessment period** (date of assessment up to three months before the surgery); and the **post-index event period**, starting one day after the index date and ending 30 days after patients being discharged from the hospital or death, whichever occurred first (Figure 1).

Figure 1. Study design

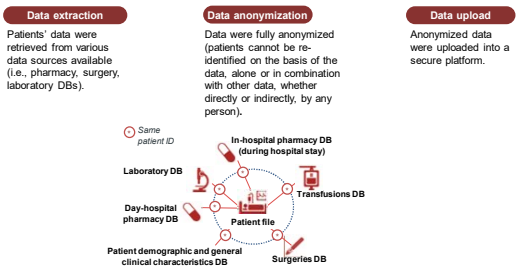


PBM, Patient Blood Management

THE VARIABLES. For all surgeries included in the study, patient's demographics, surgery details, iron deficiency anemia, treatments received, RBC transfusions, Length of Hospital Stay (LOHS) and other clinical outcomes were collected. Transfusion policy applied by the hospital was also collected.

DATA SOURCE. The collection approach consisted of retrieving data of patients who underwent surgery before or after the PBM program implementation from hospital Databases (DB) (Figure 2). Data collected were fully anonymized at hospital-level and uploaded into a platform.

Figure 2. Data collection and management process



DB, Database

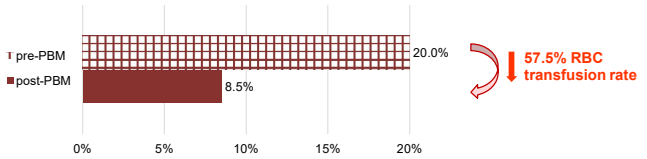
DATA ANALYSIS. Descriptive analysis of demographic and clinical characteristics of surgeries performed in both study cohorts was performed. Logistic regression models were performed to assess the impact of PBM on post-surgery RBC transfusion rate, including potential confounders (age, period, gender, inpatient blood loss volume).

RESULTS

PBM implementation and impact on the RBC transfusion rates.

- RBC transfusion rate after the surgery was 20.0% (n=654) for pre-PBM cohort, decreasing to 8.5% (n=399) for post-PBM patients' cohort, globally showing a reduction of 57.5% in the RBC transfusion rate between pre- and post-PBM (Figure 3).

Figure 3. Post-surgery RBC transfusion rates before (pre-PBM) and after (post-PBM) the implementation of PBM



PBM, Patient Blood Management; RBC, Red Blood Cells

- The logistic regression model, which included analysis with additional potential confounders (as described in Table 1: age, period, gender, inpatient blood loss volume), showed that PBM implementation at the hospital was associated with a lower need for RBC transfusions [Odds Ratio, OR of 0.313 (Confidence Interval, CI 95%: 0.273-0.360)] (Table 1, upper panel).
- In addition, the use of the intravenous (IV) iron ferric carboxymaltose (FCM) prior surgery in post-PBM cohort, received by 13% of total post-PBM patients, was associated with a higher decrease in RBC transfusion rate (OR=0.114, 95% CI: 0.074-0.177) (Table 1, lower panel).

Table 1. Impact of PBM implementation on RBC transfusion rate after surgery (logistic regression model)

	OR (95% CI)	p-value
Age at index date (years)	1.041 (1.035-1.048)	<0.0001
Post-PBM period (reference pre-PBM period)	**0.313 (0.273-0.360)**	**<0.0001**
Female (reference male)	1.354 (1.175-1.560)	<0.0001
Inpatient blood loss volume (mL)	1.003 (1.003-1.004)	<0.0001

	OR (95% CI)	p-value
Age at index date (years)	1.041 (1.035-1.048)	<0.0001
Post-PBM period with FCM (reference pre-PBM period)	**0.114 (0.074-0.177)**	**<0.0001**
Post-PBM period without FCM (reference pre-PBM period)	0.350 (0.303-0.404)	<0.0001
Female (reference male)	1.421 (1.232-1.639)	<0.0001
Inpatient blood loss volume (mL)	1.003 (1.003-1.004)	<0.0001

CI, Confidence Interval; FCM, ferric carboxymaltose; OR, Odds Ratio; PBM, Patient Blood Management; RBC, Red Blood Cells

Hospital characteristics. After PBM implementation in 2013, the site implemented a restrictive transfusion policy (i.e., when Hemoglobin concentration was <7 g/dL to 8 g/dL).

Patient demographics.

- Overall, data from 7,972 orthopedic surgeries were included in the study (3,267 surgeries included in the pre-PBM cohort and 4,075 in the post-PBM).
- Out of the 7,972 procedures, 6,438 and 1,534 were hip and knee replacement surgeries, respectively.
- Surgeries were more frequently associated with female patients, 56.8% (59.0% in pre-PBM cohort and 55.2% in post-PBM cohort). The percentage of female patients was slightly higher in the subset of patients receiving knee replacement (73.5%) compared to hip replacement (52.8%)
- Patients had a mean (SD) of 64.1 (12.3) years of age at time of surgery.

Surgery characteristics.

Mean (SD) time surgery duration was 1.1 (0.5) and 1.2 (0.5) hours in pre- and post-PBM cohorts, respectively (Table 2).

In terms of bleeding, pre-PBM cohort patients lost a mean (SD) of 176.5 (69.8) mL of blood during the surgery and post-PBM patients 207.2 (78.5) mL. In most cases, spinal anesthesia was used (overall, 99.1%, n=7,897) (Table 2).

Table 2. Surgery characteristics

	pre-PBM (N=3,267)	post-PBM (N=4,705)
Mean (SD) time of surgery (hours)	1.1 (0.5)	1.2 (0.5)
Mean (SD) blood loss volume (mL)	176.5 (69.8)	207.2 (78.5)
Use of spinal anesthesia	3,237 (99.1%)	4,660 (99.0%)

PBM, Patient Blood Management; SD, Standard Deviation

CONCLUSIONS

The present study provides a comprehensive description of the PBM impact on post-surgical RBC transfusion rates. In spite of the fact that hospital practices may have changed throughout the years (i.e., additional factors influencing the two patients' cohorts), the study showed how PBM implementation, and particularly of the use of FCM to treat preoperative iron deficiency anemia, had a significant impact on the reduction of post-surgery RBC transfusions.

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